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Benner et al.

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(54) NON-SLIDING AND NON-SUTURED CONTACT LENS SYSTEM FOR OPHTHALMIC PROCEDURES

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(51) Int. Cl.
A61B 3/00 (2006.01)
A61B 3/125 (2006.01)
(Continued)

(52) U.S. Cl.
CPC *A61B 3/125* (2013.01); *A61B 3/117* (2013.01); *A61B 17/0231* (2013.01); *A61F 9/00* (2013.01);
(Continued)

(58) Field of Classification Search
CPC .. A61B 3/14; A61B 3/13; A61B 3/102; A61B 3/103; A61B 3/107; A61B 3/117;
(Continued)

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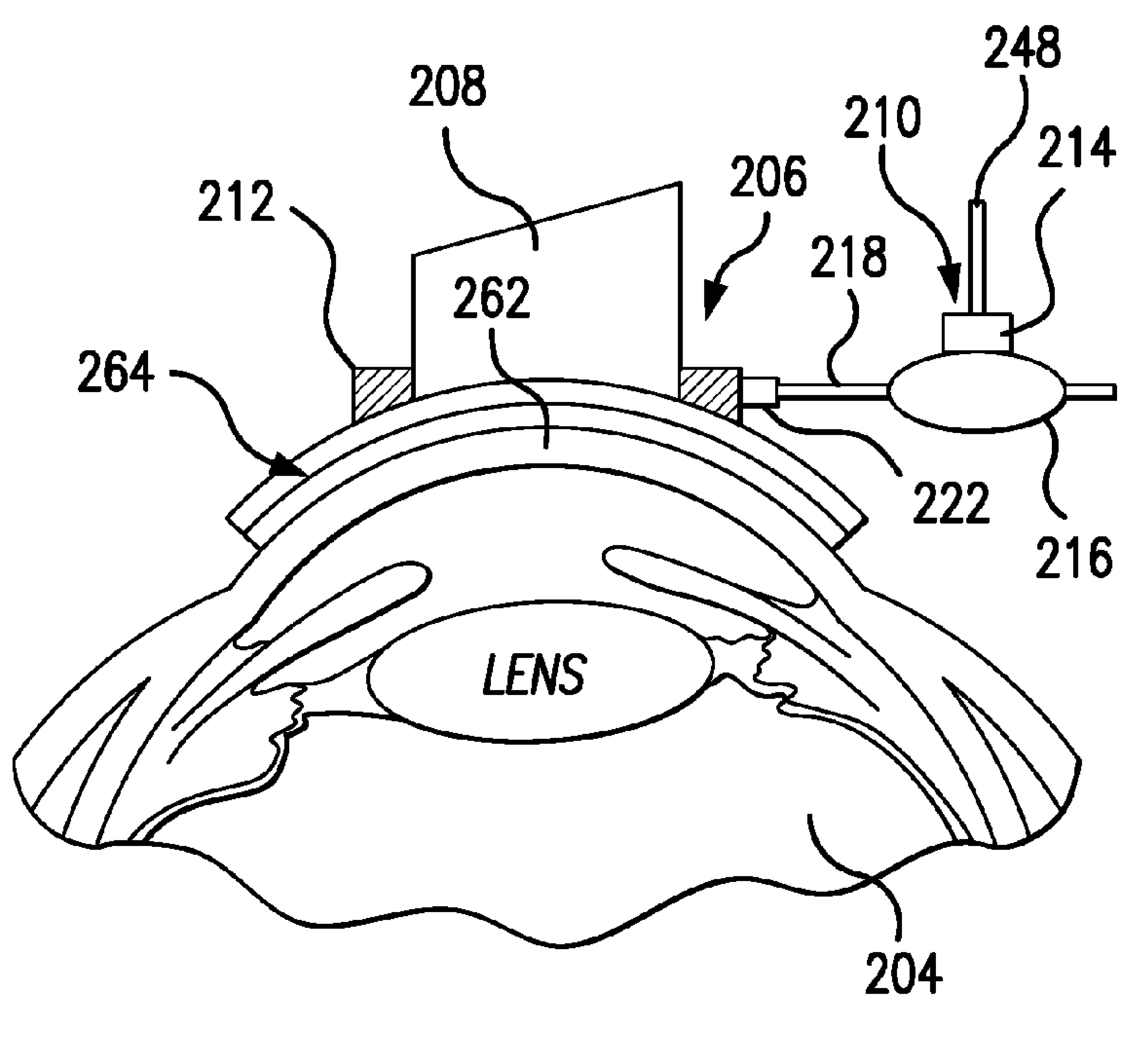
Primary Examiner — Mustak Choudhury
(74) *Attorney, Agent, or Firm* — Rosenberg, Klein & Lee

(57) ABSTRACT

A contact lens assembly for non-sliding, non-sutured, hands-free ophthalmic procedures utilizes a magnetically actuated anchoring mechanism operatively coupled between the contact lens assembly and a modified eye speculum applied to eyelids during ophthalmic procedure. The anchoring mechanism is configured with magnetically cooperating anchoring members, one coupled to the contact lens assembly, and another secured to a wire loop member of the modified eye speculum. After the eye speculum is applied to the eyelids to displace and stabilize the eyelids and secure the anchoring member in place, and the contact lens assembly is placed on the cornea of the eye and centered, he magnetically cooperating anchoring members are brought in contact, and thus secure the contact lens assembly at the surgical site.

16 Claims, 15 Drawing Sheets



Related U.S. Application Data

which is a continuation of application No. 15/497,827, filed on Apr. 26, 2017, now Pat. No. 9,936,871.

(60) Provisional application No. 62/329,292, filed on Apr. 29, 2016.

(51) **Int. Cl.**

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A61B 17/02	(2006.01)
A61B 3/117	(2006.01)
G02C 7/04	(2006.01)
A61B 17/00	(2006.01)

(52) **U.S. Cl.**
CPC ***G02C 7/04*** (2013.01); *A61B 2017/00946* (2013.01); *A61F 2009/0052* (2013.01)

(58) **Field of Classification Search**
CPC A61B 3/125; A61B 3/152; A61B 3/1173; A61B 17/0231; A61B 2017/00946; A61F 9/00; A61F 9/009; A61F 9/008; A61F 9/00825; A61F 9/00834; A61F 9/00745; A61F 9/00821; A61F 2009/0052; A61F 2009/0087; G02C 7/04
See application file for complete search history.

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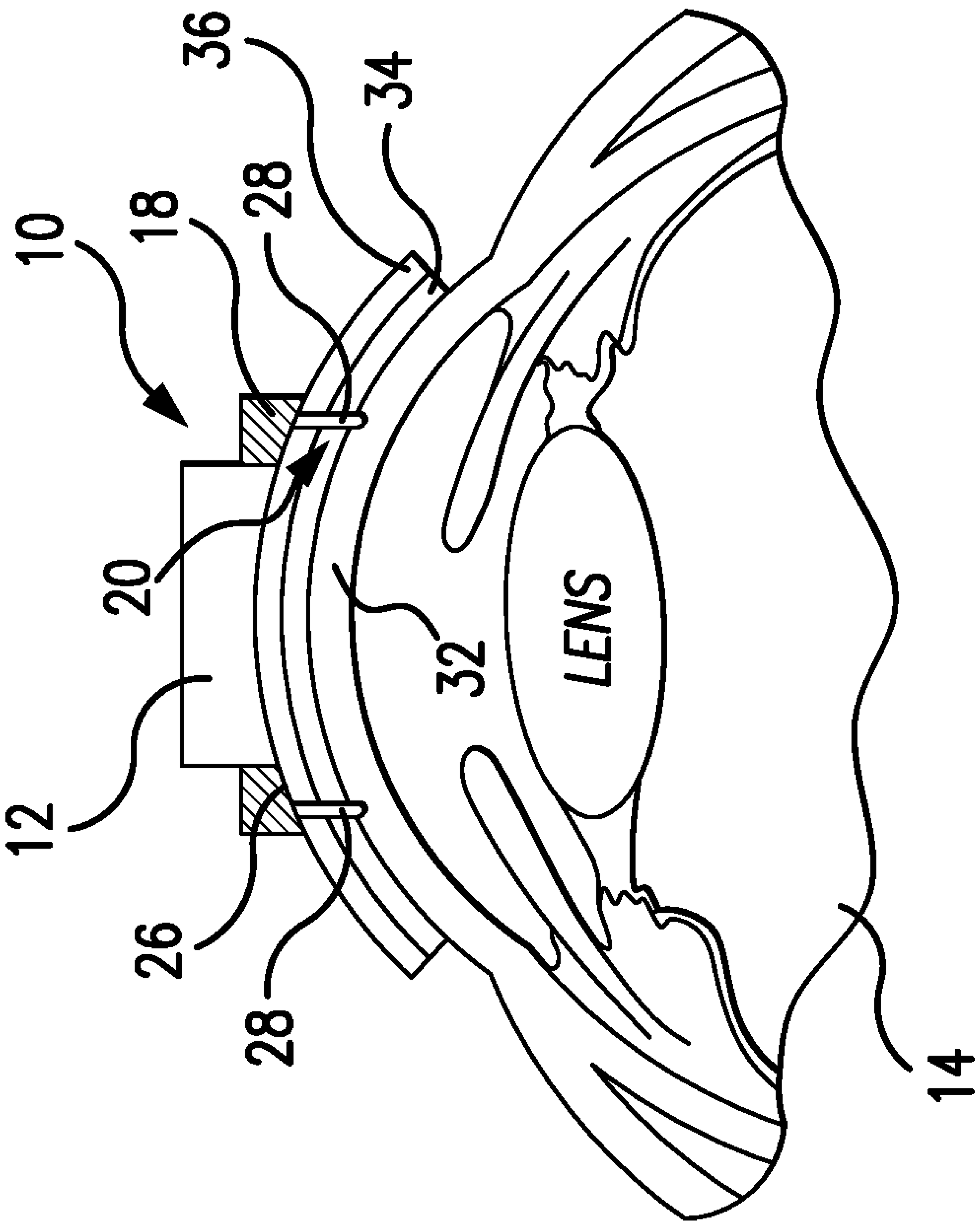
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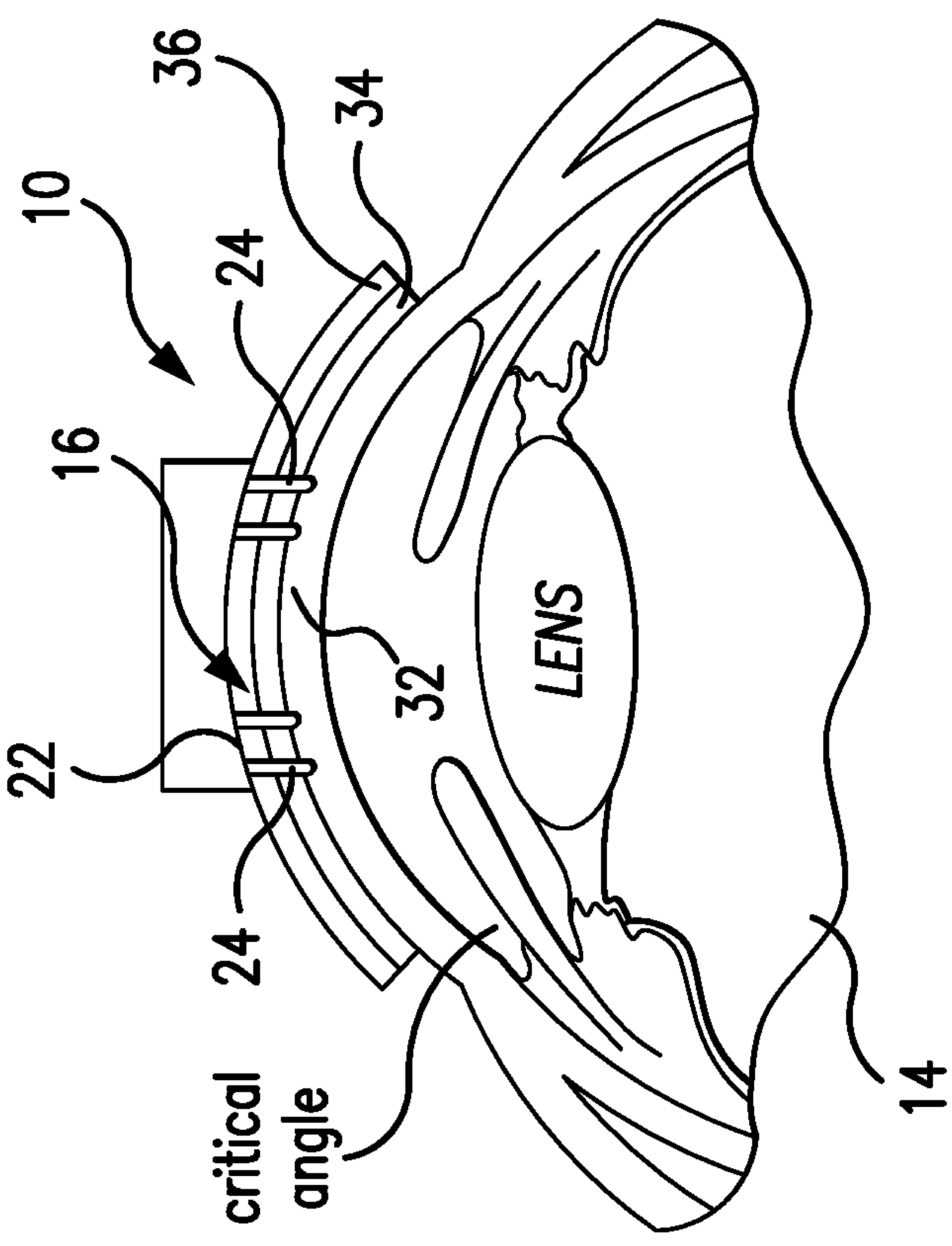
LENS

FIG. 1B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LENS
critical angle

FIG. 1A

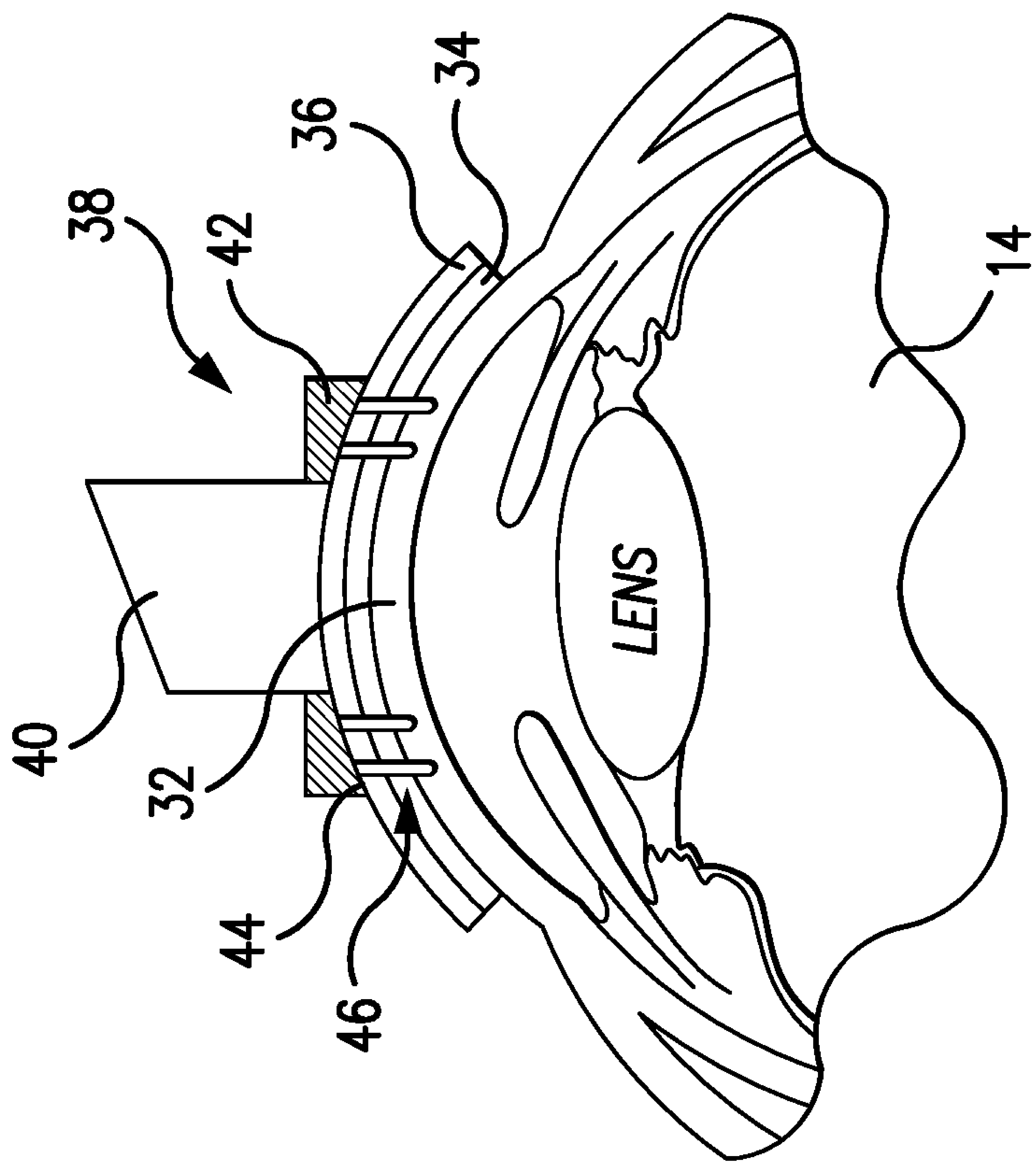

FIG. 2

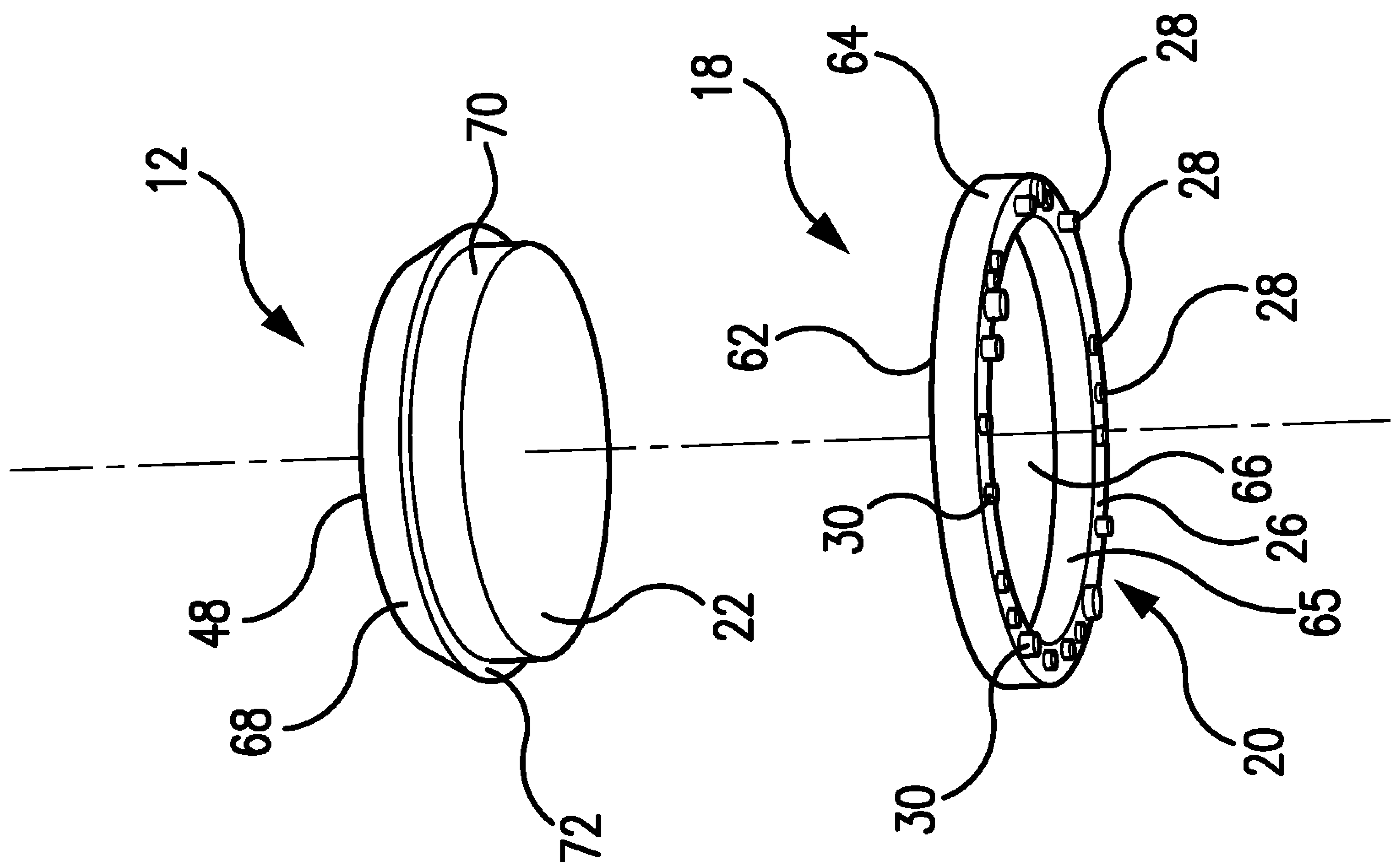
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FIG. 3B

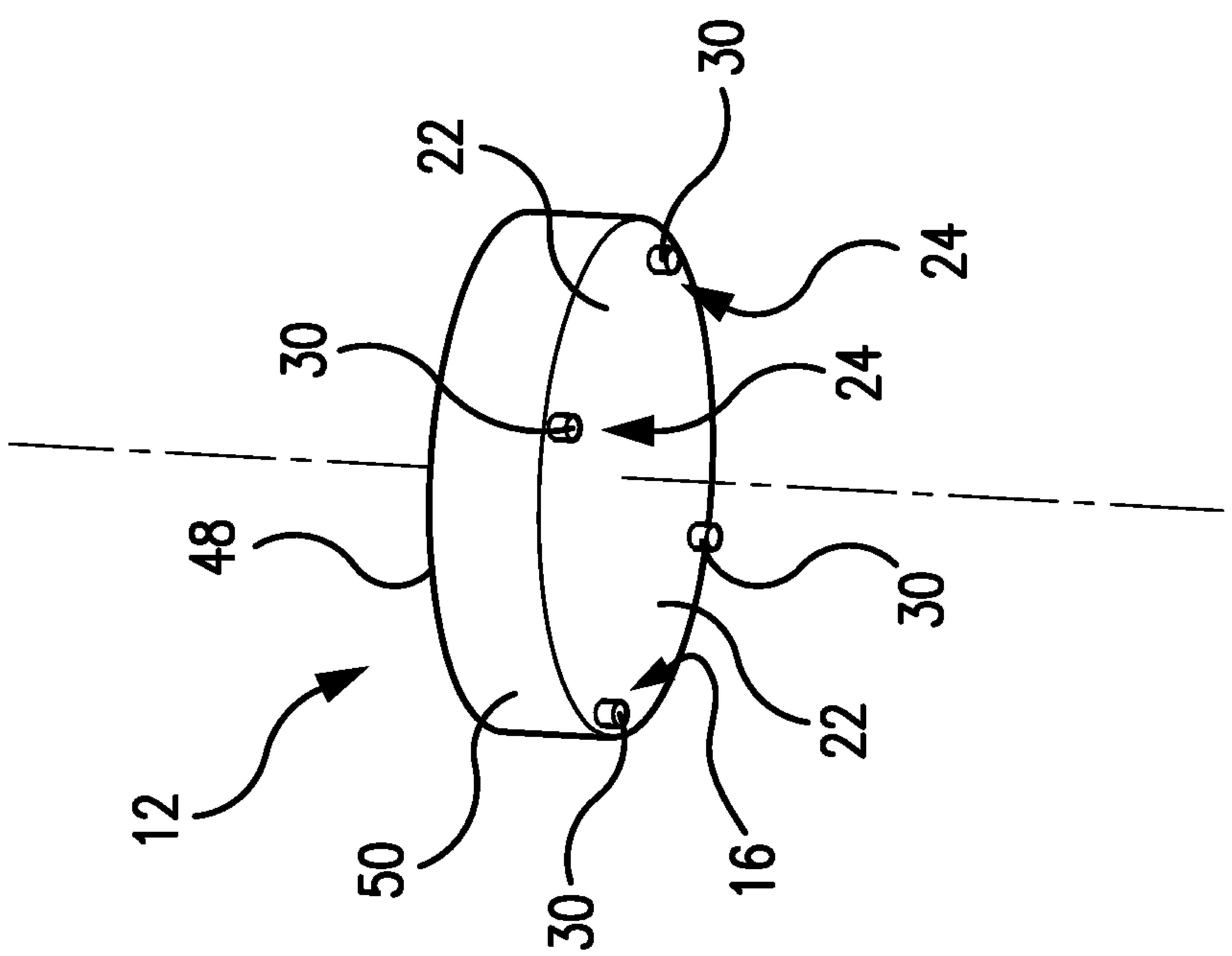
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FIG.3A

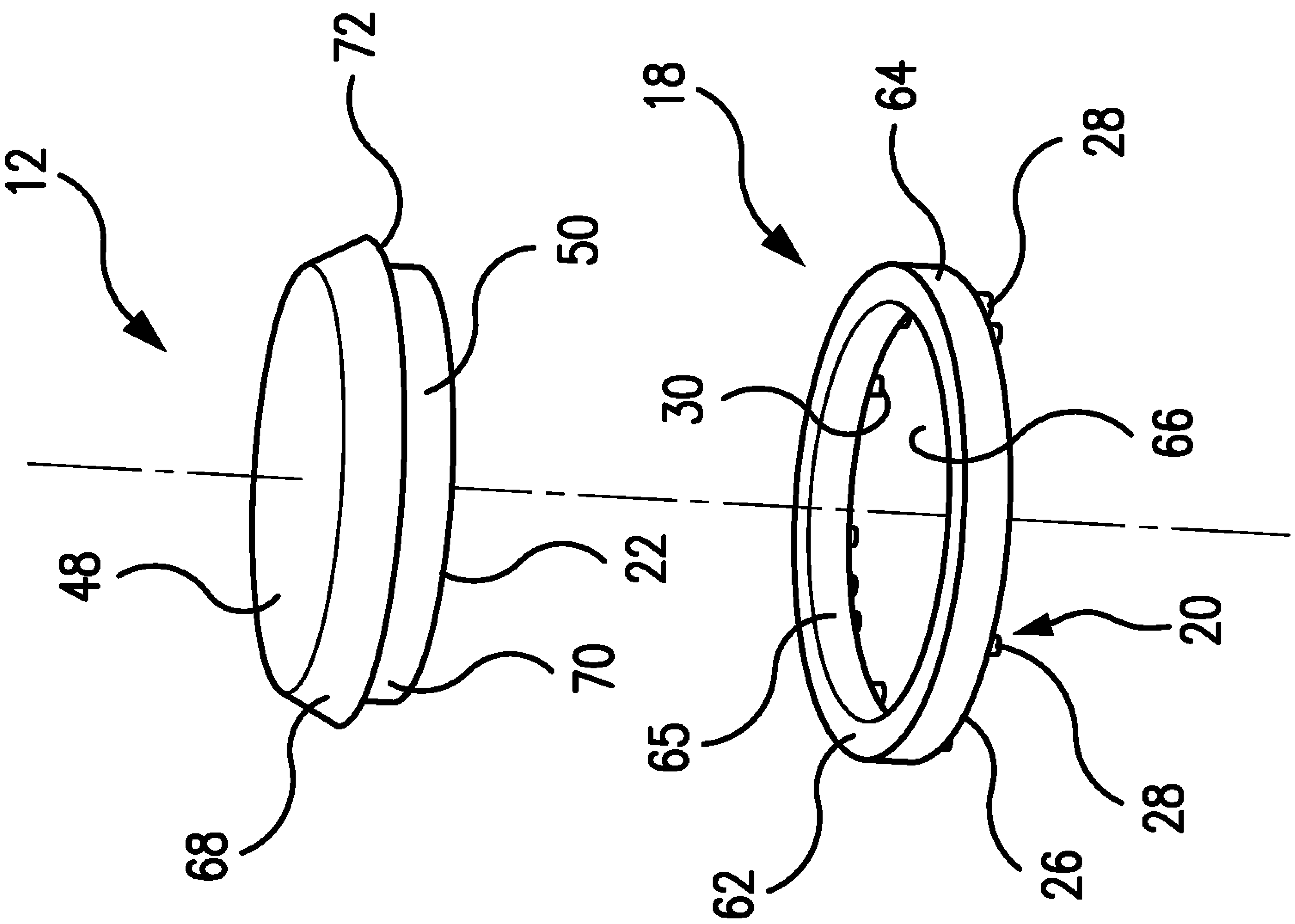

FIG. 4B

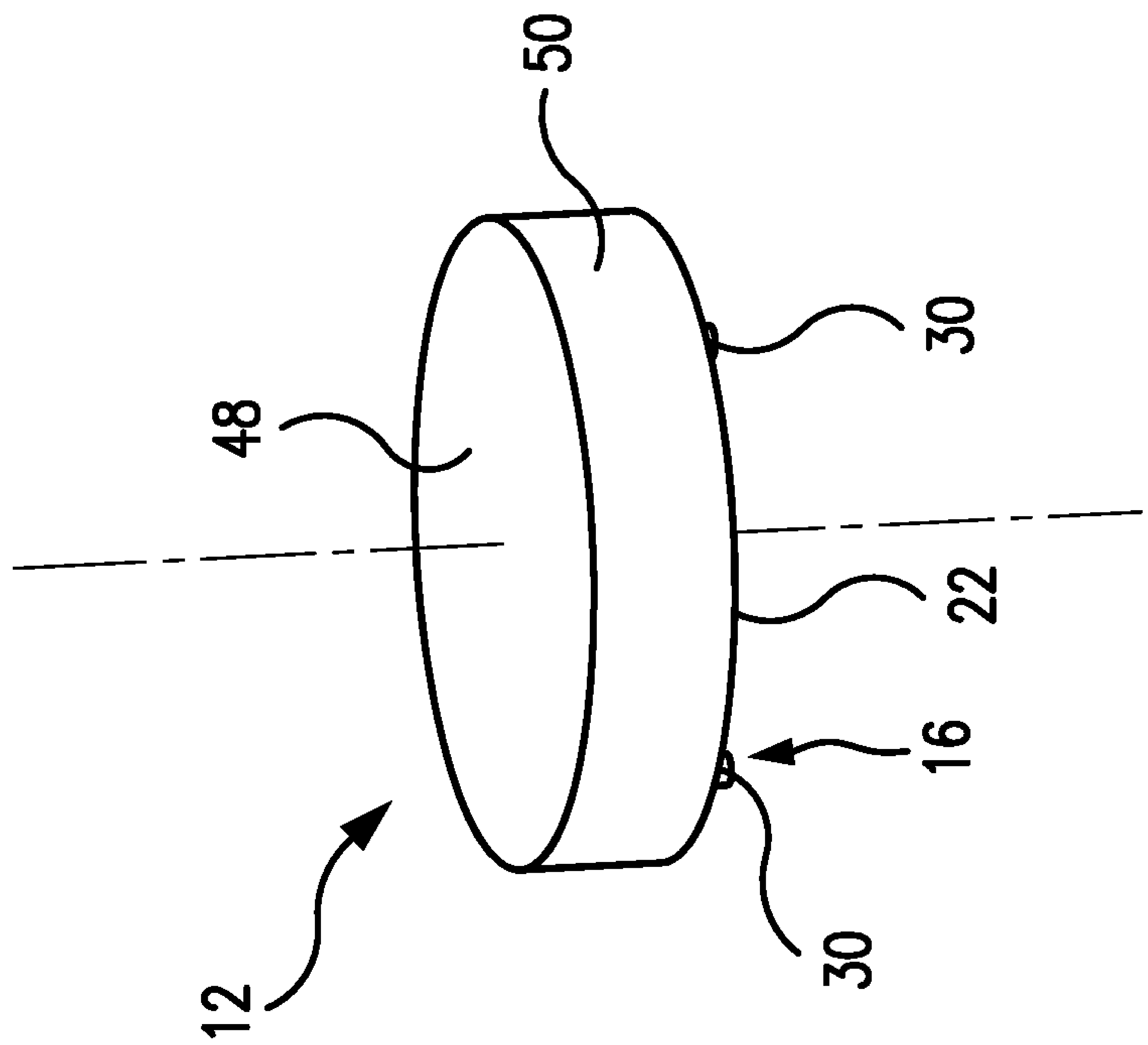

FIG. 4A

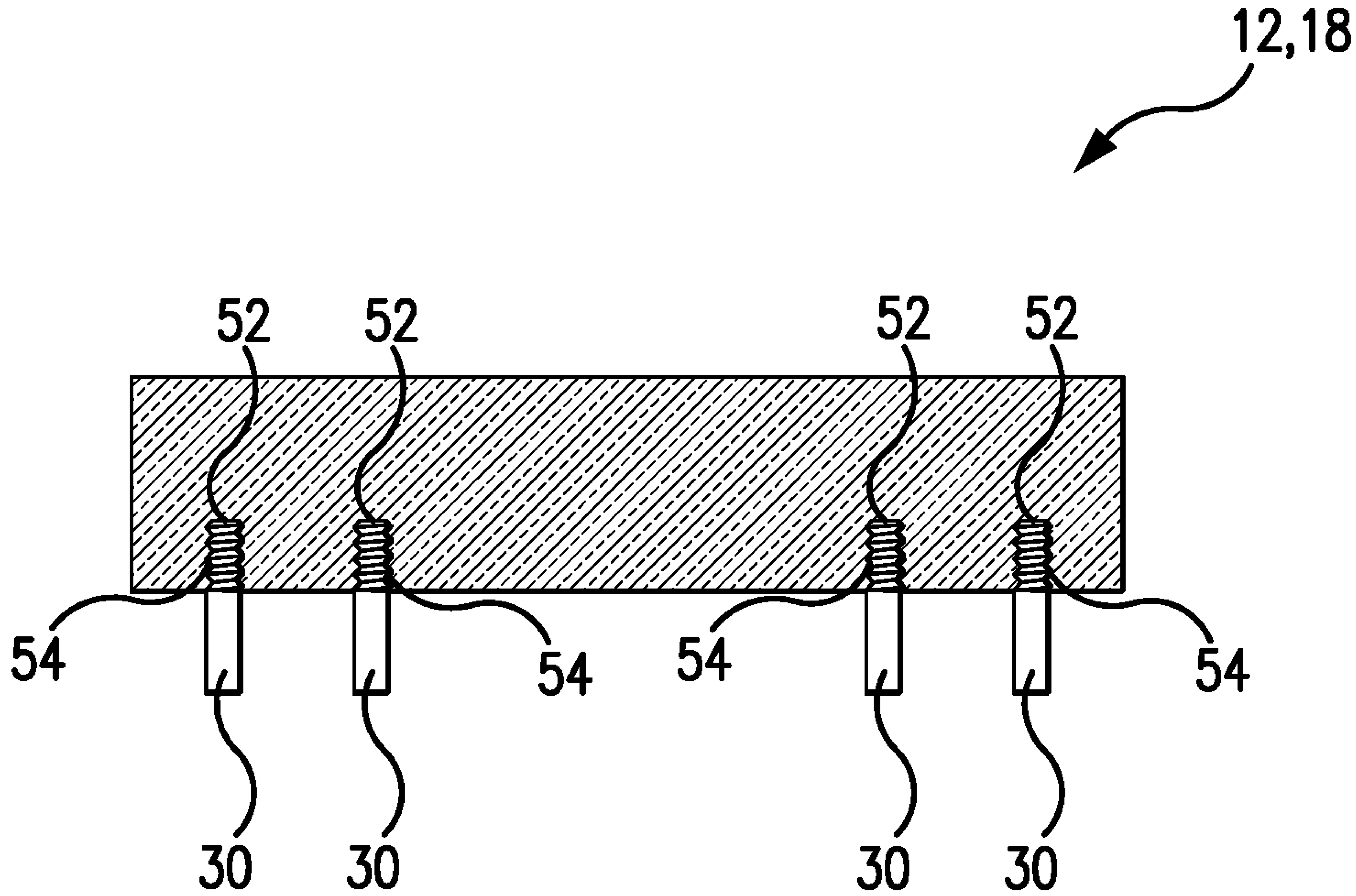
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FIG. 5A

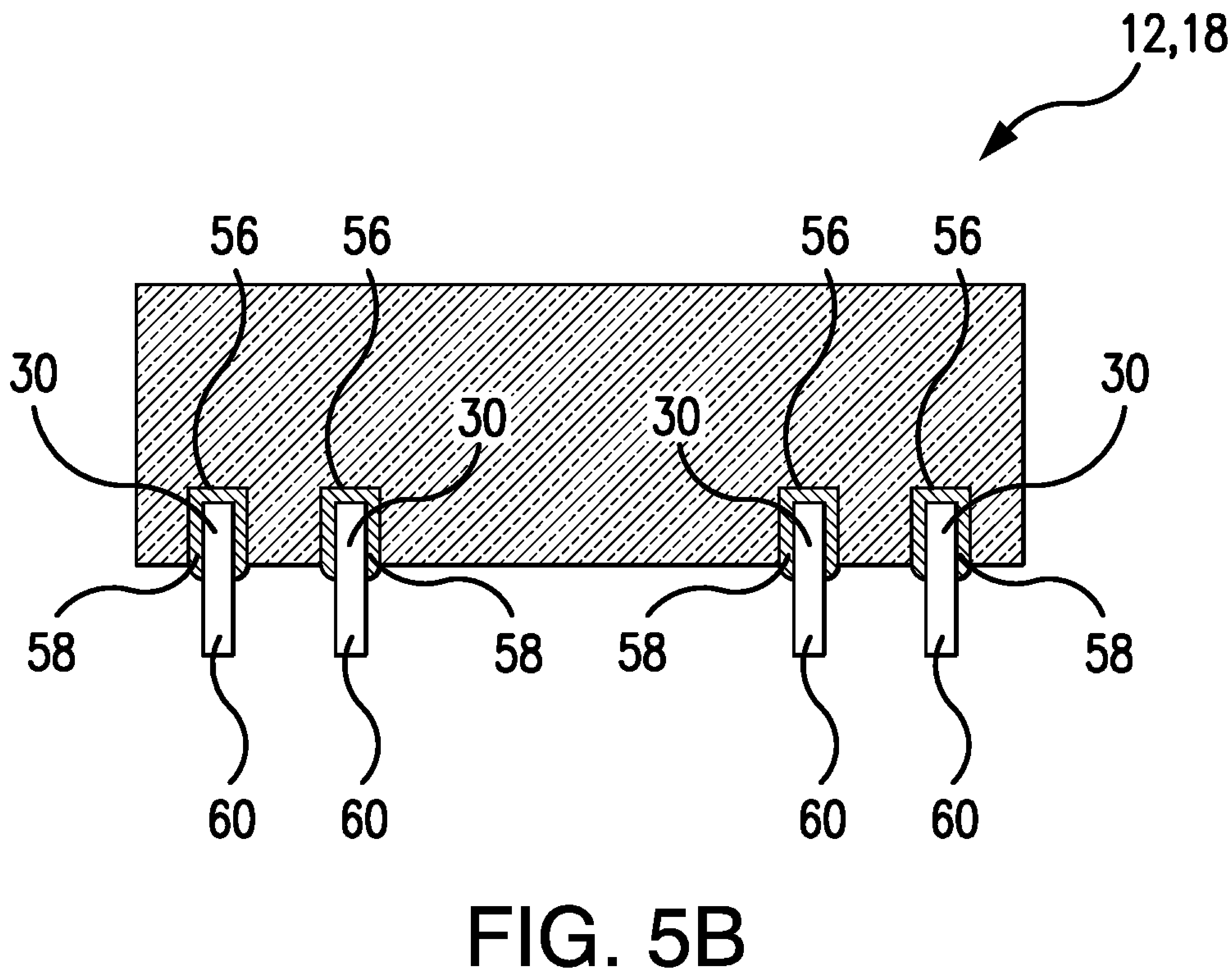
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FIG. 5B

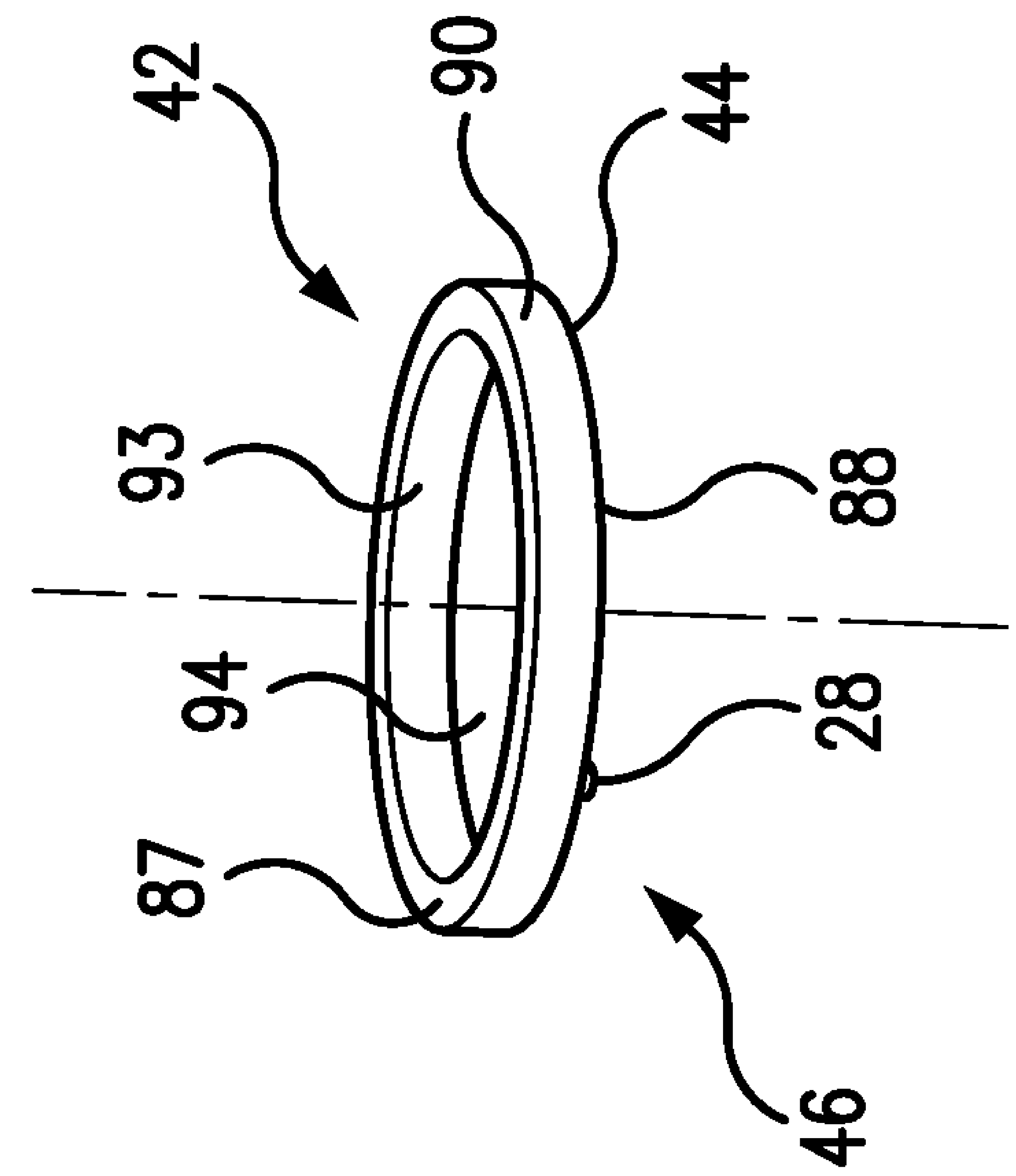
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FIG. 7A

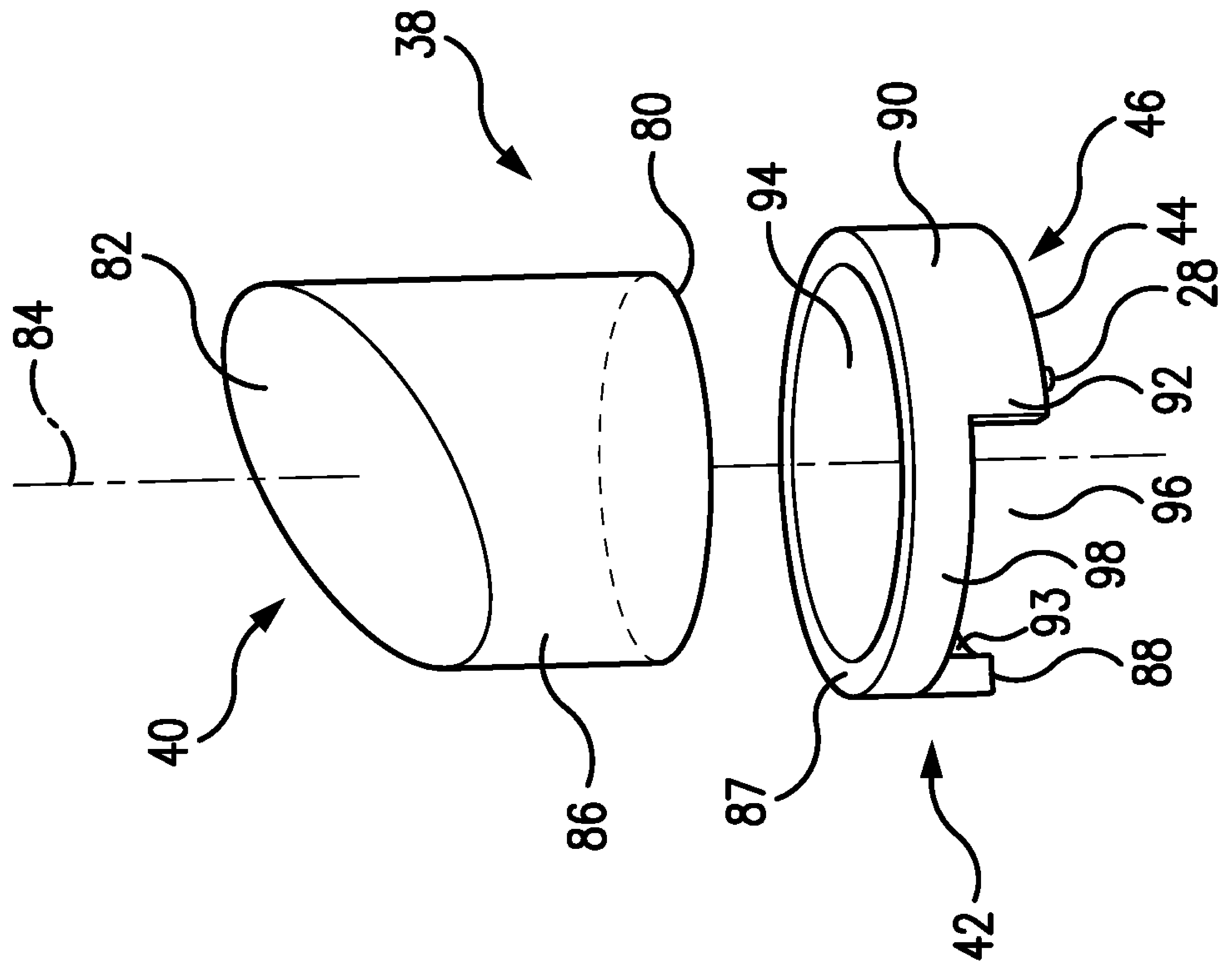
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FIG. 6A

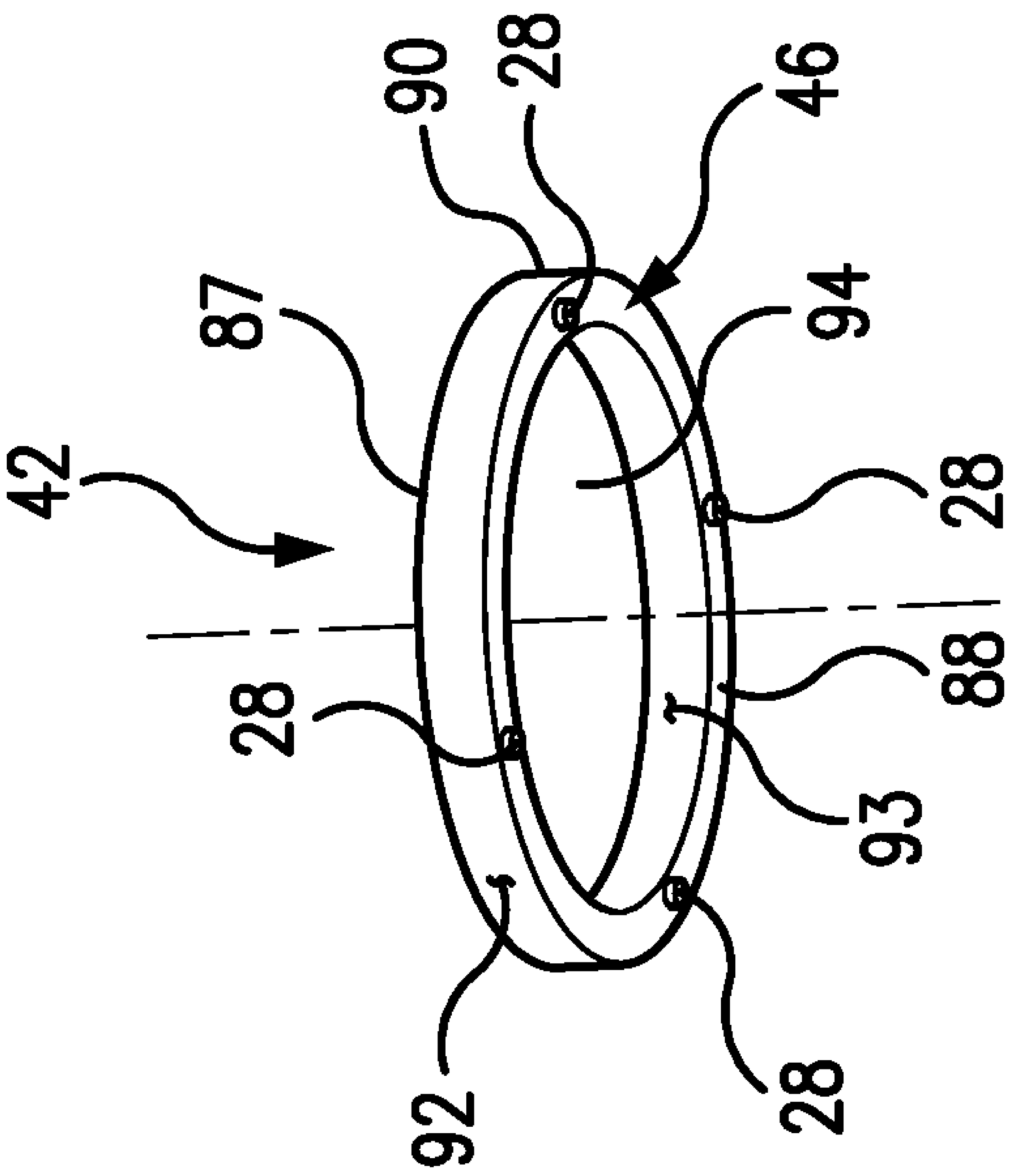
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FIG. 7B

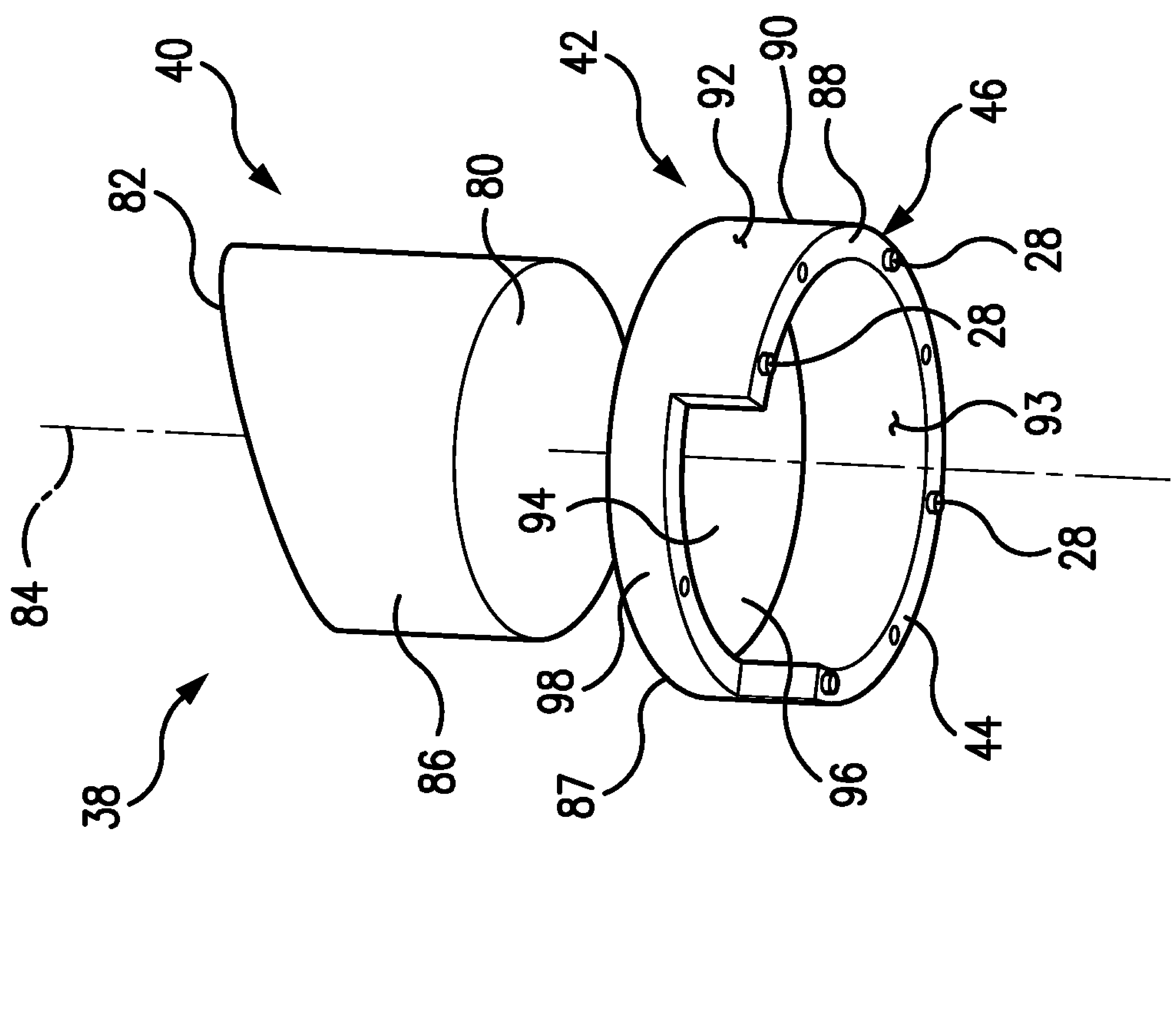
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FIG. 6B

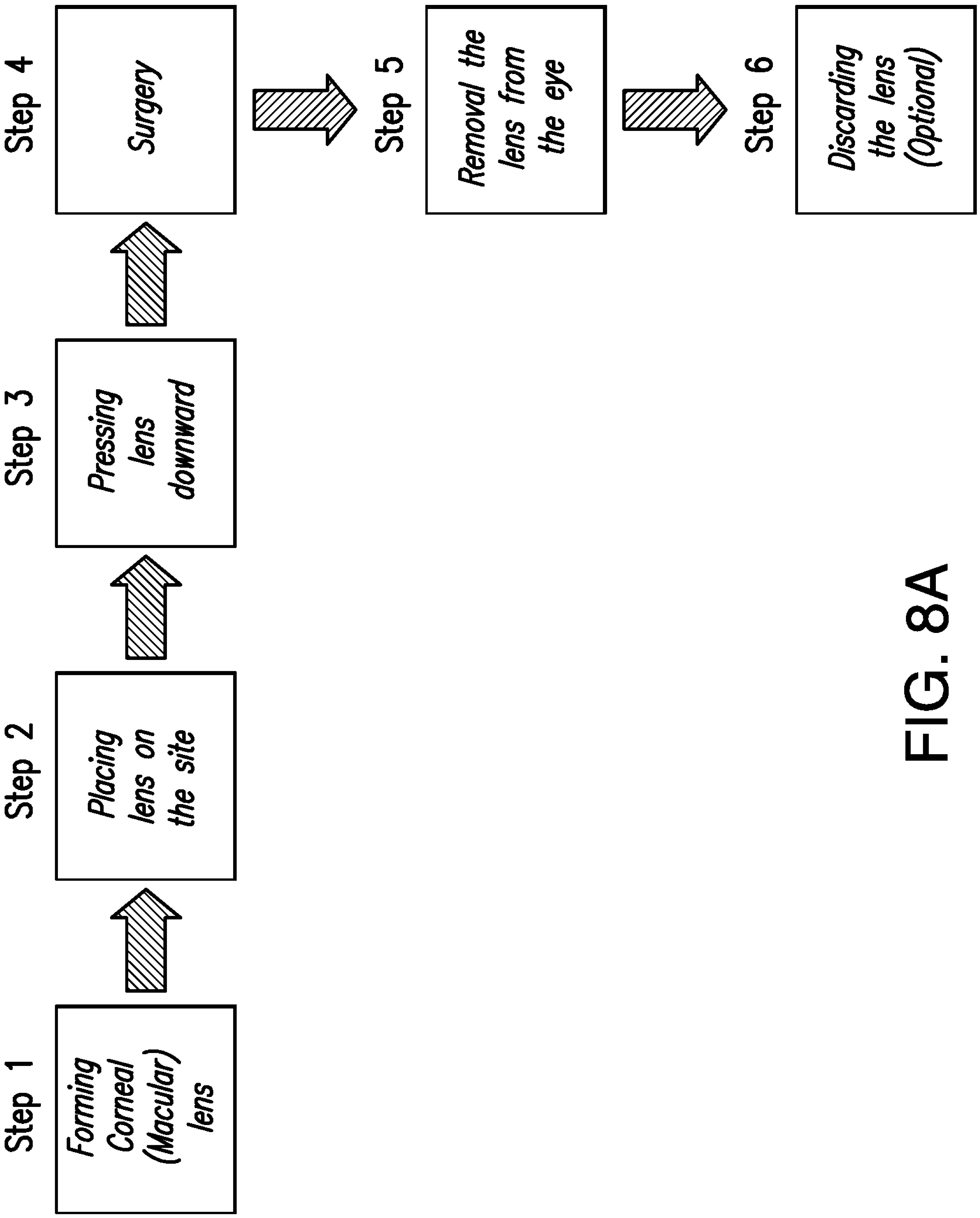
Step 1
Forming Corneal (Macular) lens
Step 2
Placing lens on the site
Step 3
Pressing lens downward
Step 4
Surgery
Step 5
Removal the lens from the eye
Step 6
Discarding the lens (Optional)

FIG. 8A

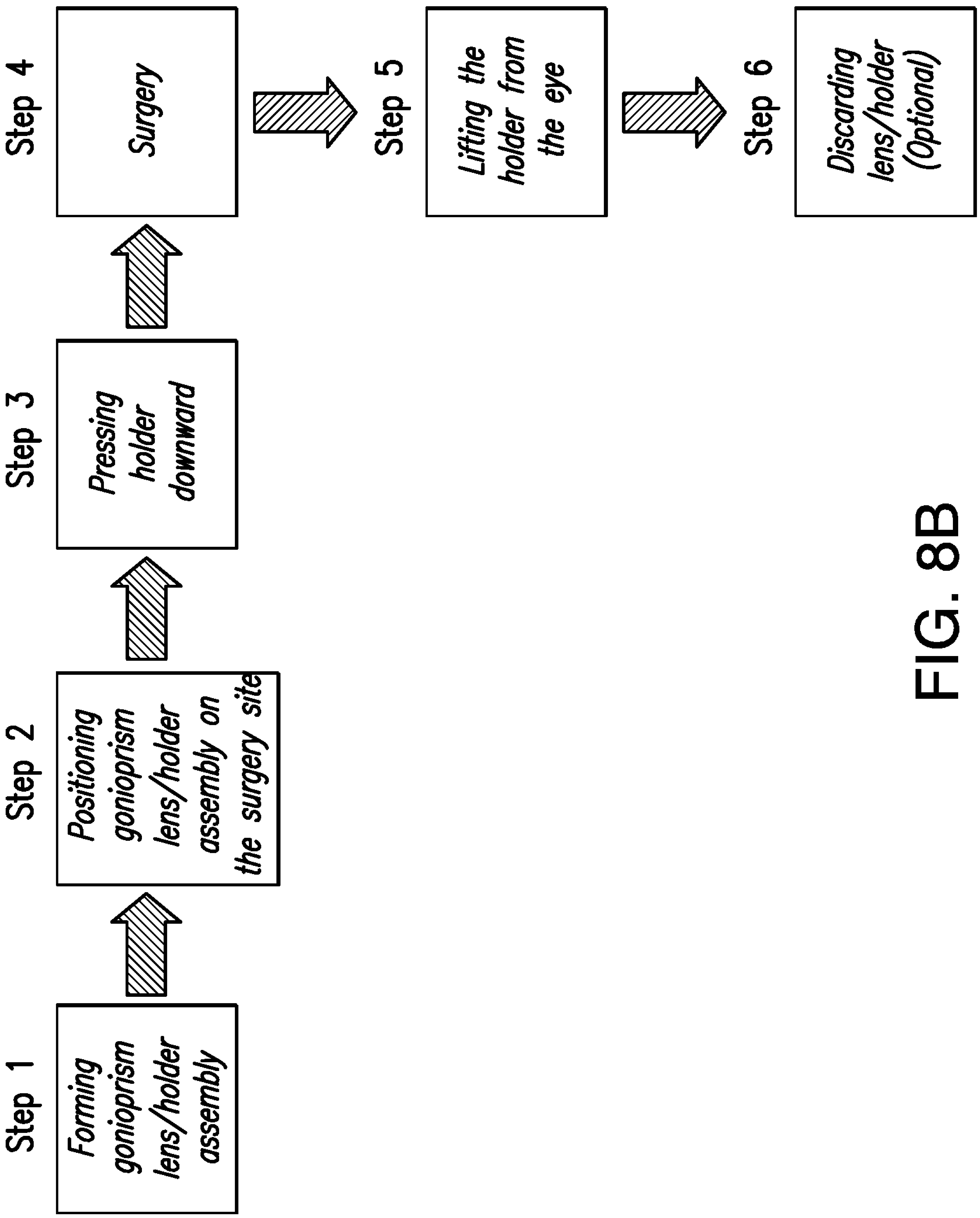
Step 1
Forming gonioprism lens/holder assembly
Step 2
Positioning gonioprism lens/holder assembly on the surgery site
Step 3
Pressing holder downward
Step 4
Surgery
Step 5
Lifting the holder from the eye
Step 6
Discarding lens/holder (Optional)

FIG. 8B

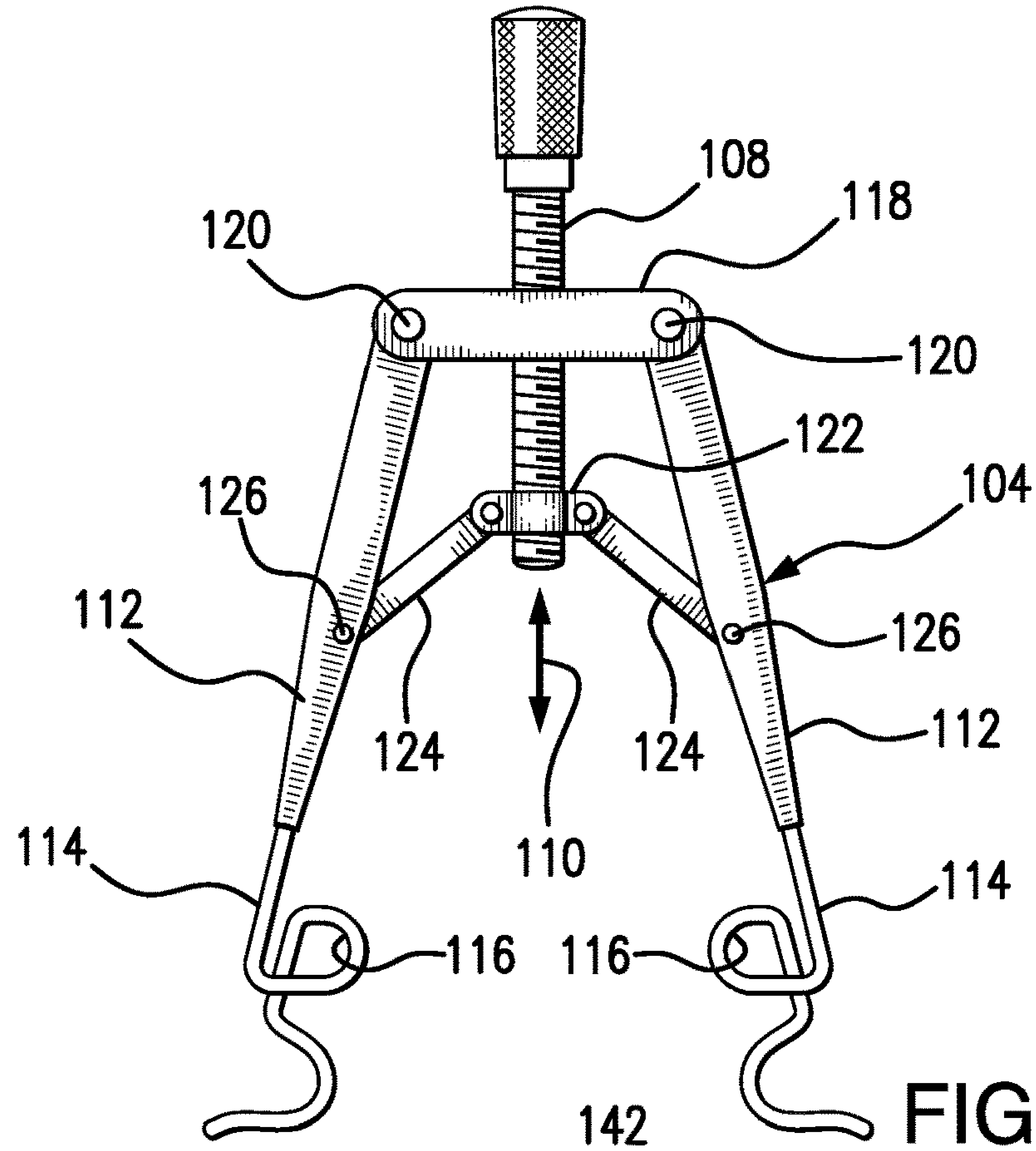
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FIG. 9

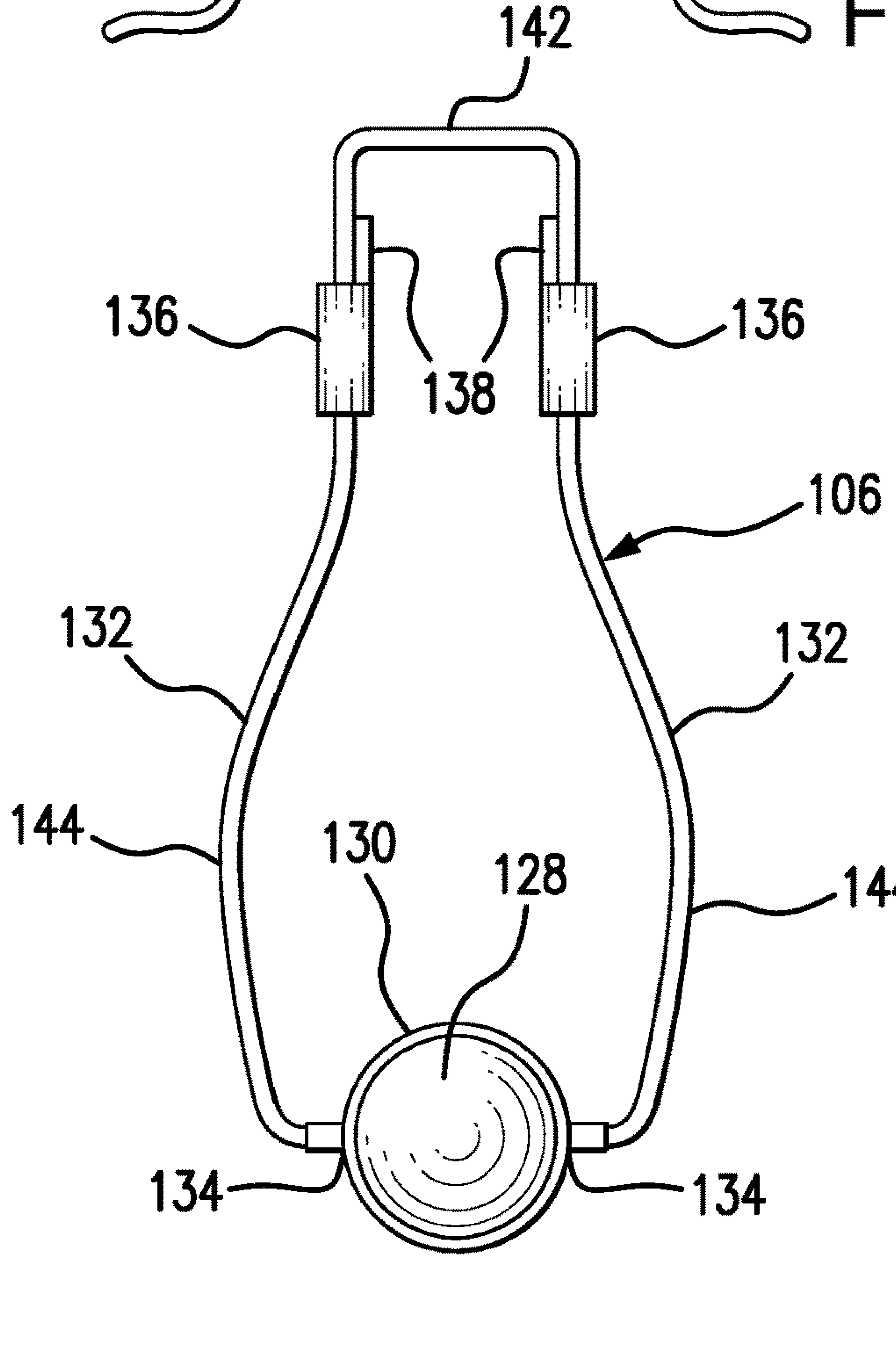
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FIG. 10

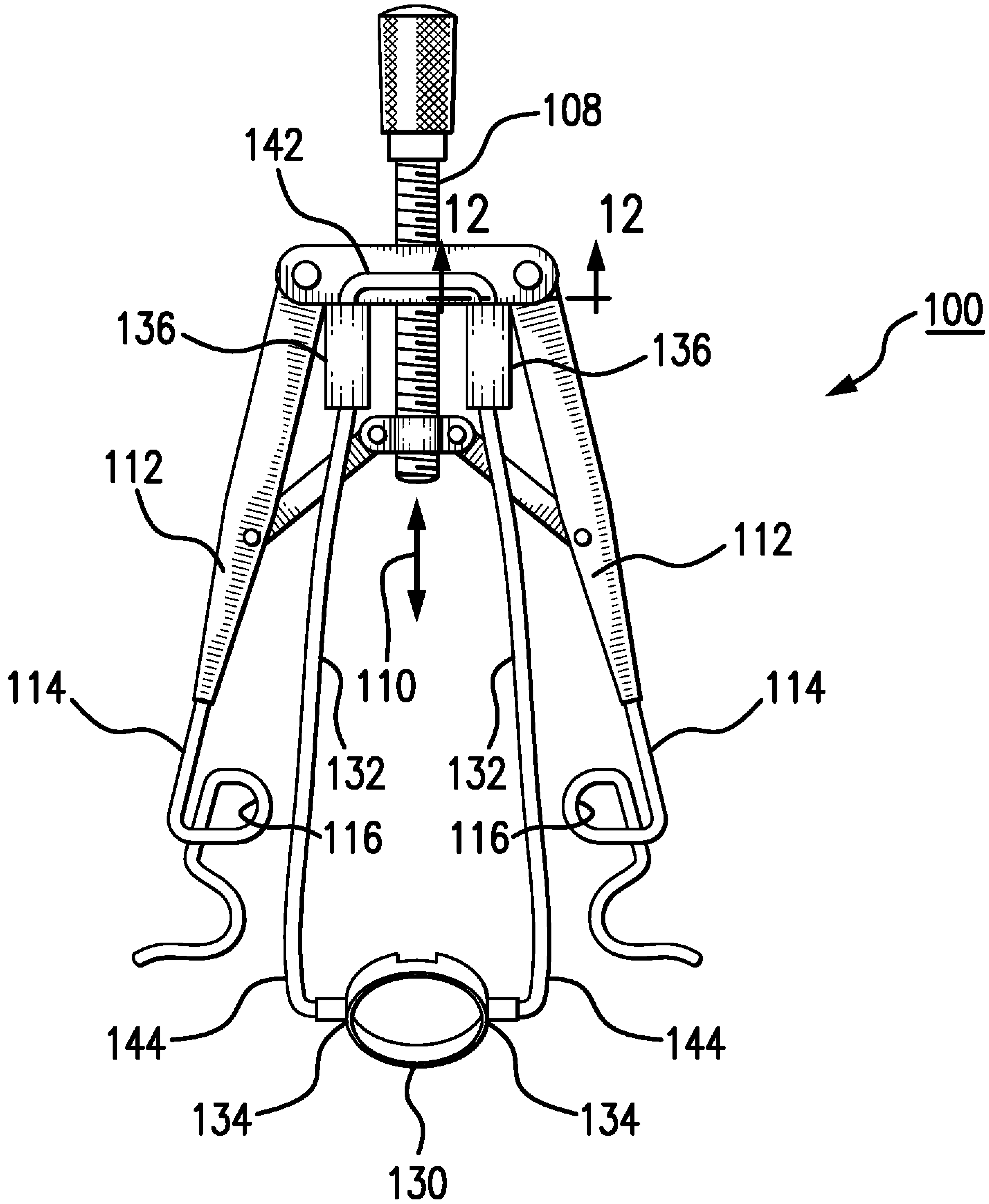
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FIG. 11

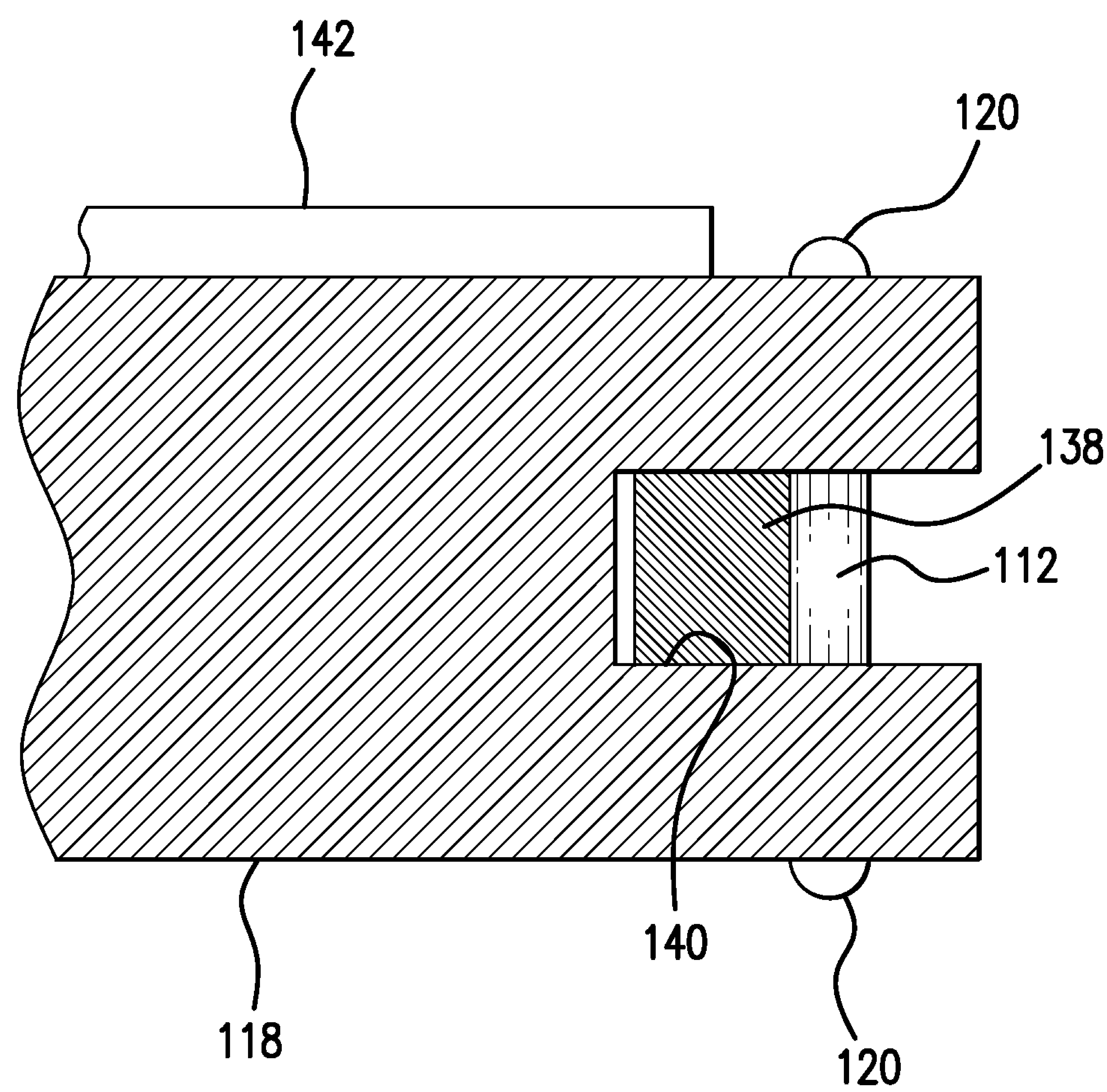

FIG. 12

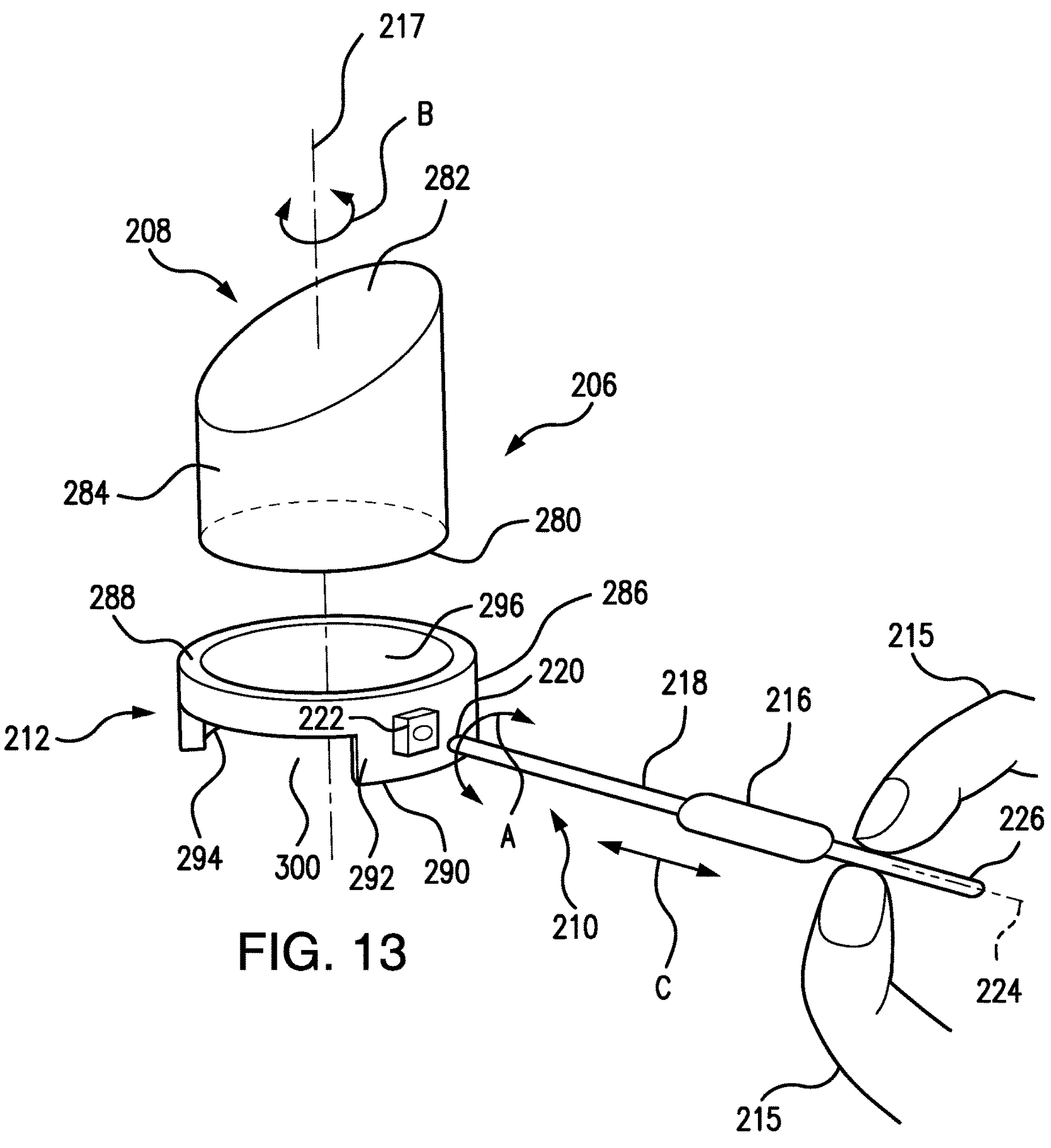
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FIG. 13

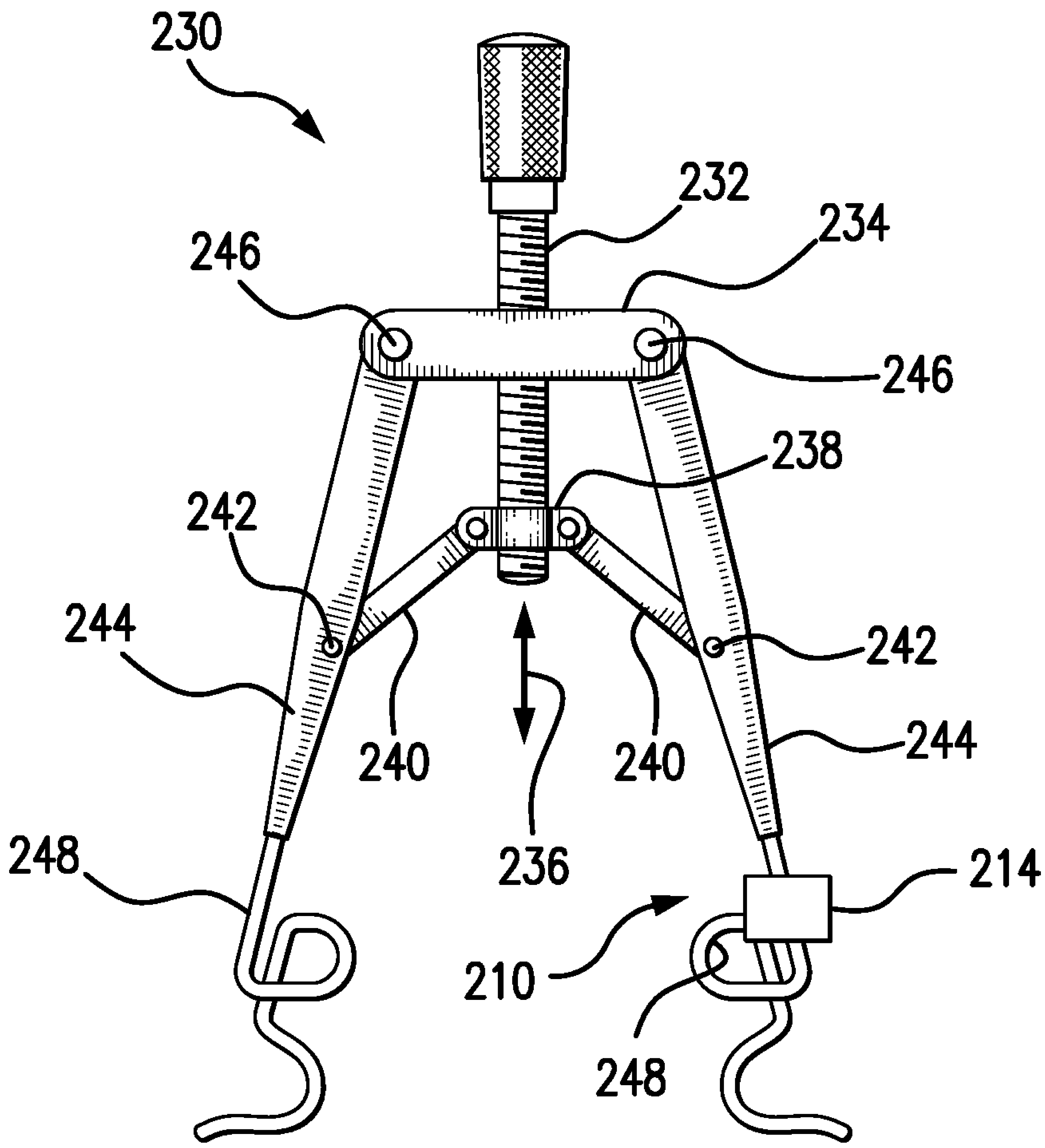
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FIG. 14

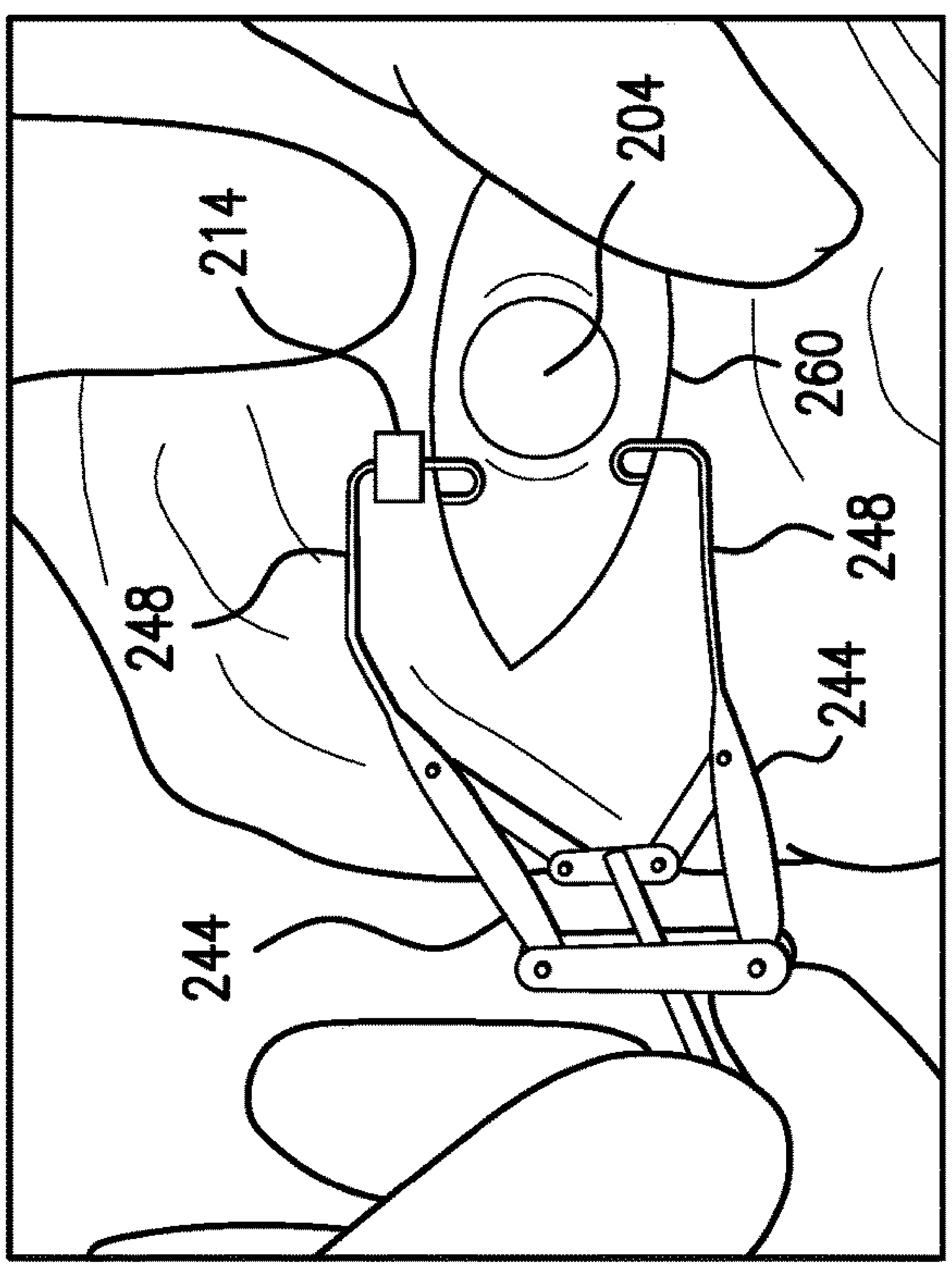

FIG. 15A

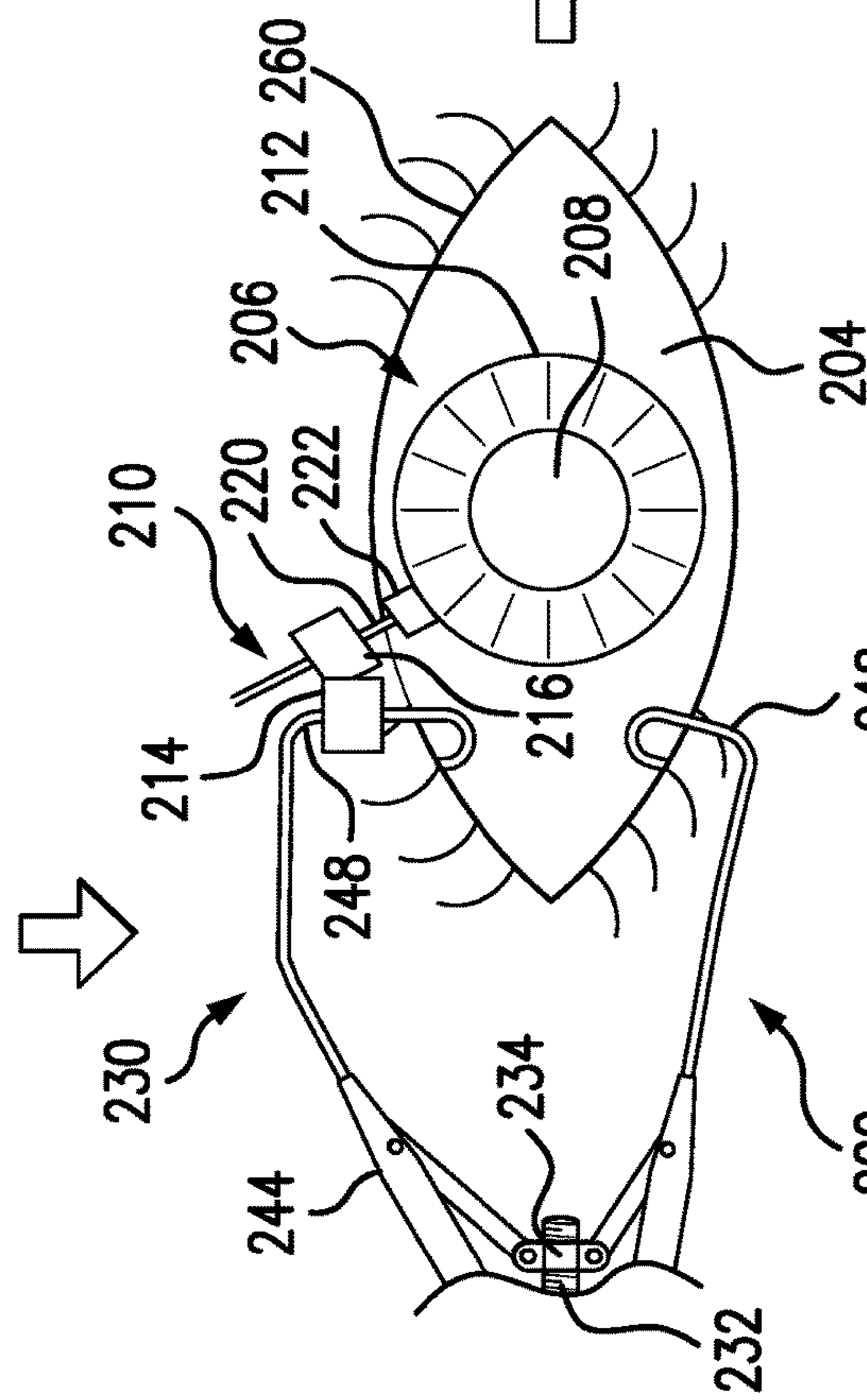

FIG. 15B

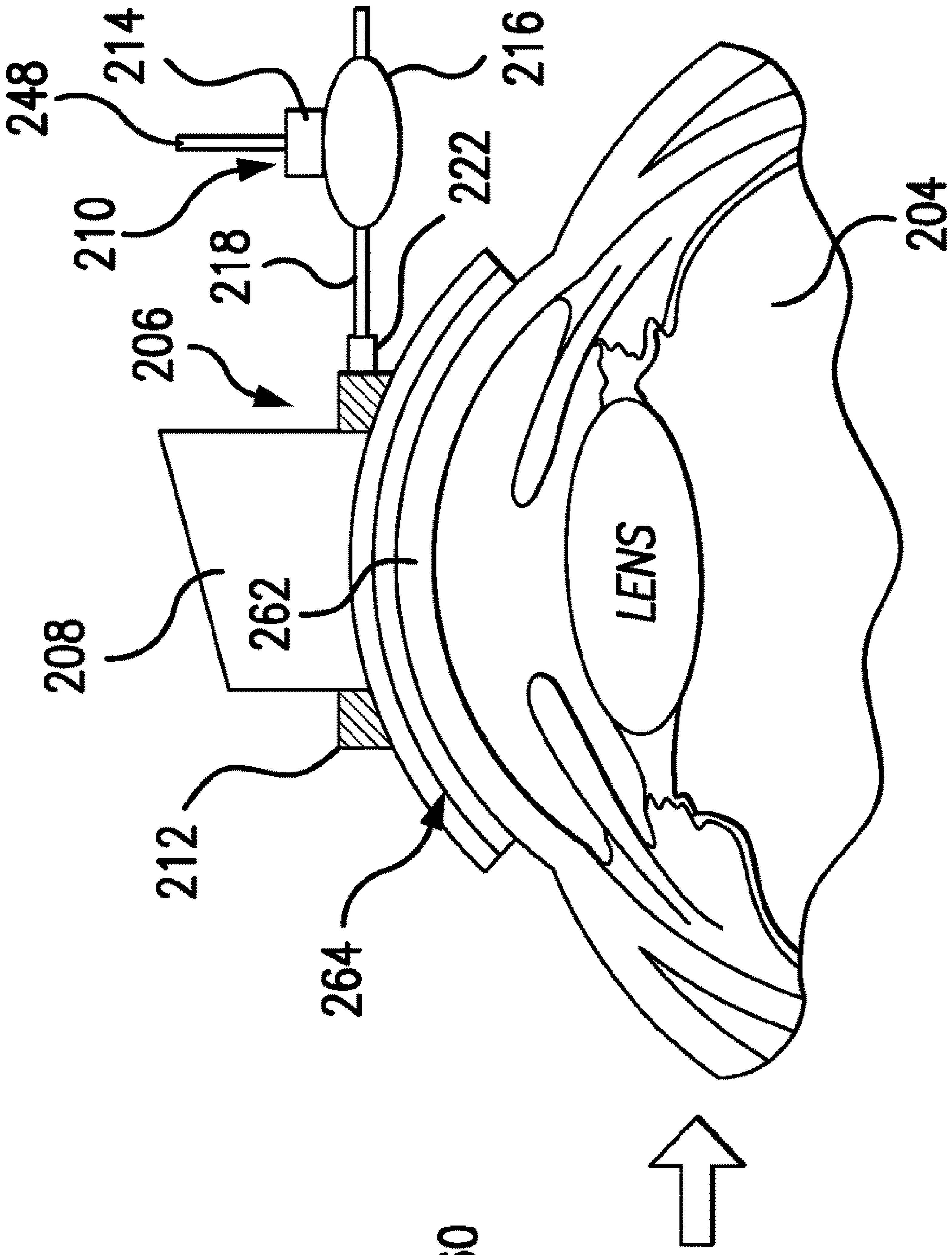

FIG. 15C

NON-SLIDING AND NON-SUTURED CONTACT LENS SYSTEM FOR OPHTHALMIC PROCEDURES

RELATED APPLICATIONS

This Application is a Continuation-in-Part Application of patent application Ser. No. 15/902,578 filed on 22 Feb. 2018, currently pending, which is a Continuation of patent application Ser. No. 15/497,827 filed on 26 Apr. 2017, issued as U.S. Pat. No. 9,936,871, which was based upon Provisional Patent Application Ser. No. 62/329,292 filed on 29 Apr. 2016.

FIELD OF THE INVENTION

The present invention is directed to the field of ophthalmic surgical intervention, and particular to contact lens used in ophthalmic surgeries.

More in particular, the present invention is directed to corneal (and macular) contact lenses, as well as gonioprisms, used in vitreoretinal surgeries (procedures), which allow a surgeon to visualize the macula and other structures of the eye under surgery at high magnification.

In addition, the present invention is directed to contact lenses used in ophthalmic procedures which are configured with an anchoring mechanism which stabilizes and centers the lens on the cornea of the eye (or other desired site of procedure) in a "hands-free" manner without the need for monitoring and manual positioning of the contact lens during ophthalmic procedures.

Further, the subject system is directed to a contact lens anchoring system which does not require suturing for stabilization and centration during the ophthalmic procedure, and thus is free of superficial bleeding from the conjunctiva caused by the suturing.

The present invention is further directed to a non-sutured and hands-free contact lens anchoring system for ophthalmic surgeries which effectively stabilizes and centers the contact lens on the cornea of the eye during surgery and which is prevented from sliding on the area of interest by a magnetic connection mechanism configured for quick attachment of the contact lens to an eyelid speculum used in the ophthalmic procedure, thus temporarily anchoring the contact lens to the cornea. The subject magnetic mechanism is easily deactuated to remove the lens from the eye when the ophthalmic procedure is completed.

Additionally, the present system is directed to a suture free, non-sliding stabilization anchoring system for a corneal (or macular) contact lens, as well as gonioprism contact lens, used in vitreoretinal surgeries, which is configured with a pair of magnetically cooperating members, where one magnetically cooperating member is secured to the eyelid speculum, and another magnetically cooperating member is attached to a contact lens holder (of the contact lens itself) via a wire member, which is secured to the contact lens or the contact lens holder, and where during the procedure the first and second magnetically cooperating members are brought in contact to magnetically engage one with another, thus anchoring the contact lens or the contact lens holder to the cornea without any trauma to the eye tissues.

In overall concept, the present invention is directed to a contact lens assembly for ophthalmic procedures performed with the use of an eyelid speculum for displacing the eyelids of a patient, where the contact lens assembly includes a contact lens adapted for contacting an eye of the patient, a contact lens holder secured to the contact lens, and an anchoring magnetically actuated mechanism releasably secured between the contact lens holder and the eyelid speculum for anchoring and stabilizing the contact lens (and/or the contact lens holder) at a predetermined positional location during the ophthalmic procedure, where the anchoring mechanism includes a wire member coupled to the contact lens holder and a pair of magnetically cooperating units, one of which is positioned on the wire member to being displaced therealong, and another of which is secured to the eyelid speculum. When the eyelid speculum is applied to the eyelids, and the contact lens (with the contact lens holder) is positioned on the eye under surgery, the magnetically cooperating units are brought in contact one with another for magnetically supported interconnection therebetween resulting in anchoring and stabilization of the contact lens (and/or the contact lens holder) in the predetermined position on the eye undergoing the ophthalmic procedure.

BACKGROUND OF THE INVENTION

Corneal contact lenses are a critical part of vitreoretinal surgery, especially macular surgery. The contact lenses allow a surgeon to visualize the macular as well as other structures of the eye at high magnification. Surgeons typically employ a separate lens that can be placed directly on the eyeball and allow focusing to be extended to the retina and other areas in the back of the eyeball.

In order to be effective, a contact lens must be stably positioned and centered on the cornea of the eye at the site of the surgery. This is difficult to achieve due to the cornea curved contouring. The slipperiness is made worse by the use of viscous coupling agents (such as, for example, viscoelastics or hydroxymethyl cellulose), which are used to avoid bubble formation beneath the contact lens during the surgery.

The lens placed on the eyeball floats on a thin layer of fluid and tends to slide about the surface of the eye. In order to overcome the sliding displacement and to hold the lens in place, a surgeon or a surgeon's assistant constantly monitors the lens position and uses a rod or other extension (handle) to push the lens back to a desired location. In order to perform this task, the surgeon or surgeon's assistant must have a profound experience in vitreoretinal surgery which is not always the case.

For example, U.S. Pat. No. 5,070,290, describes the gonioscopy, which is a technique used for viewing inner portions (such as the retina and the anterior chamber angle) of the eye for evaluation, management, and classification of normal and abnormal structures of the eye. The gonioscopy technique uses devices known as gonioscopes to enhance visibility of the trabecular meshwork and anterior chamber angle during surgical procedures. The gonioscope is handheld by a surgeon in place over the patient's cornea while he/she performs the surgical procedure.

The gonioscope described in U.S. Pat. No. 8,070,290 includes the Hill gonioprism positioned on a patient's eye. The gonioscopic optical element, which includes one or several lens, such as optical prism(s), is received in a lens retainer, and a handle or a grip is attached to the lens retainer. During the surgical procedure, the gonioscopic optical element is positioned over or on the patient's eye, e.g. the cornea of the eye.

A light source is used during the surgery which emits light toward the patient's eye. The light source may be configured such that light from the source illuminates the patient's eye, the anterior chamber, and the eye structures near the anterior chamber, e.g. trabecular meshwork, such that one or more of these structures reflect(s) light incident from the light source.

The light source and the prism(s) is (are) arranged in such a fashion that the light from the light source is reflected by the patient's eye (or specific optical structures), traverses the gonioscopic prism(s), and is redirected, e.g., refracted and diffracted, by the gonioscopic prisms. An image is formed of at least part of the patient's eye and this image is viewed using a microscope.

The handle of the gonioscope described in '290 patent is used to stabilize and centralize the entire gonioscope structure. This arrangement generally requires assistance of a surgeon assistant to manipulate the handle of the gonioscope during the procedure.

Landers has improved upon the gonioscope prism requiring manual manipulation of the handle during the ophthalmic procedure surgery, and provided a "hand-free" solution for the problem which eliminates the need for a surgeon assistant to manually stabilize and centralize the contact lens.

The Landers' system uses a lens ring which circumferentially envelopes sides of the contact lens, and serves as the lens holder. To stabilize and centralize the contact lens at the desired site during the procedure, the lens ring is secured to the conjunctiva/sclera with a pair of fixation sutures. The contact lens is placed inside the lens ring which remains in place by the fixation sutures, and thus, the contact lens is maintained in place and sutured throughout the duration of the macular surgery.

Fixation sutures, however, are not welcomed by a majority of ophthalmologists, especially glaucoma surgeons, due to traumatic effects of the fixation sutures to the cornea or sclera of the eye. In addition to the traumatic nature of the fixation sutures (which typically cause bleeding which can obscure view of the surgical site), if the sutures are excessively tight, the cornea can be disturbed and the sutures may break during the surgery, which is definitely a disadvantage of the suturing approach. On the other hand, if the sutures are too loose, the displacement of lens may occur, which can undermine the surgery efficiency.

Since the Landers development, various solutions for "suture-less" contact lens stabilization have been developed. For example, as presented in U.S. Pat. No. 5,963,301, the lens is constructed with a flange that is shaped to conform to the general curvature of an average eye. In order to be attached to the eye surface, and thus stabilizing the lens in place, the flange is formed with a number of peripheral openings or recesses sized to accommodate various types of instruments to be inserted into the eye during the surgery. The flange is formed with fittings to which a vacuum is applied in order to pull the flange into contact with the sclera of the eye by creating a vacuum between the flange and eye to enhance holding the lens device in position.

Another method for overcoming the problem of contact lens movement during surgery is disclosed in U.S. Pat. No. 6,120,147 where the lens are replaced with flexible lens having a relatively flexible flange which is fixed in place by capillary action.

U.S. Patent Application Publication No. 2014/0307229 and related U.S. Pat. No. 9,339,184 describe a contact lens for vitreoretinal surgery where a contact lens assembly has a central lens and a circumscribing flange. The lens has an eye contact surface shaped generally to a radius of curvature of a cornea of an eye. The flange comprises a sterile sponge-like liquid absorbent flexible material having a central aperture for fitting snuggly about an outer circumference of the lens and extending radially outward therefrom.

During the procedure, the lens is mated with a flange and the lens/flange assembly is then placed on the wetted eye of a patient. Additional wetting compound, such as sterile saline solution, is then spread onto the flange until the flange is generally situated. The lens can then be moved as necessary for viewing and the wetted flange holds the lens in a desired position.

It has been found that most of the prior art devices slide off of the cornea during the surgery. The surgeon, or the surgeon's assistant, must push the lens back to the center of the cornea a number of times during critical steps of the surgery. This may cause loss of the surgical field at a crucial moment. Thus, the suture-less systems currently available, are not preferred by many surgeons. The surgeons use the sutured lens ring even though it takes additional time and causes superficial bleeding from the conjunctiva.

It is highly desirable to provide a suture-free and hands-free non-sliding corneal contact lens anchoring and stabilization system for vitreoretinal surgery which does not require monitoring and manual positioning of the lens during the surgery and which provides hands-free effective stabilization and centralization of the lens during a surgical procedure in trauma-free manner.

One of the important topics discussed among glaucoma surgical specialists is micro invasive glaucoma surgery, further referred to herein as MIGS. The MIGS refers to a group of relatively recent glaucoma surgery techniques that are gentler and involve less tissue disruption than traditional glaucoma surgeries (such as trabeculectomy and shunts).

The glaucoma specialists indicate that there is a significant learning curve in order to master MIGS technique. Operating directly on the tiny trabecular meshwork is challenging. Obtaining visualization of the angle is the most difficult part of the learning curve and the key to mastering this surgery. The critical angle of the peripheral cornea may cause total internal reflectivity of light. For that reason, special contact lenses are needed to allow visualization of the angle structures.

Even with a surgical gonioprism, the critical angle surgery is difficult to perform. Mastering the usage of the current surgical gonioprism is a significant barrier for many surgeons. In order to visualize the angle structures, a surgeon rotates the patient's head to the side by 30°, to the microscope 30°, and to steady a hand-held surgical gonioprism on the cornea with their non-dominant hand (as shown, for example, in U.S. Pat. No. 8,070,290). This requires a significant amount of practice and steady hands. The surgeon cannot learn the technical steps of the MIG surgery, such as implanting the stent or cutting into the trabecular meshwork, until they can consistently obtain a steady view of the angle.

Glaucoma surgeons are universally opposed to placing fixation sutures. They do not want to cause any trauma to the cornea or sclera of the eye. Simplifying and improving the visualization of the critical angle during the surgery, without causing tissue injury by fixating sutures can remove the barriers that are currently limiting adoption of this newest type of glaucoma surgery, i.e., MIGS.

U.S. Patent Application Publication No. 2012/0099077 to Abt describes an ophthalmic optics (lens) which includes an aspheric anterior surface and a posterior surface having a shape substantially corresponding to the shape of a human cornea. In order to support the lens on the cornea, Abt uses a surrounding flange. Adhesive, weights or fibers (for the lens stabilization) are embedded in the tabs of the flange for registering with the sclera to create stabilization forces by the tabs' interaction with the sclera.

In Abt, the stabilizing structures (which are embedded in the tabs of the flange) do not come in contact with the tissues of the eye at the operation site. They are positioned above the eye tissues at the sclera (and thus are laterally displaced from the operation site) and "float" above the sclera area separated from the sclera tissues through the layer of the tear film and viscous layer. This "floating" on the slippery film does not provide a reliable stabilization of the lens at the operation site in Abt arrangement.

Abt's stabilizing mechanism produces shear forces displaced laterally from the cornea area and applied to the sclera (away from the cornea), and is neither formed integrally with the bottom surface of the lens nor extends vertically downward from the bottom of the lens into contact with the procedure site (such as the cornea).

The only structure in Abt system which does penetrate through the tear film of the eye are trocar cannulas. However, Abt does not consider the trocar cannulas as a mechanism for securing the optical lens to the eye of the patient. Abt emphasizes that the fastening means include packing material and/or mechanical fasteners, which are used to secure the optical lens to the patient's eye to stabilize the optical element on the eye and permit the appropriate insertion of the trocar cannulas. Thus, in Abt, trocar cannulas by themselves do not constitute the anchoring mechanism, and other fastening elements are used which facilitate the insertion of the trocar cannulas.

In Abt, the trocar cannulas are dimensioned in the mm range, and penetrate deep into sclera area. It is understood that such trocar cannulas dimensions are dictated by the operational requirements, however, they create a highly traumatic action on the tissues of the eye.

Another disadvantage of Abt is that the lens "is self-retaining on the eye through capillary attraction". The stability of the lens in Abt relies on a capillary attraction, which is not desirable since the capillary attraction forces tend to pull blood and air bubbles beneath the contact lens during surgery. This phenomenon can impair the surgeon's visualization during critical moments of surgical procedure.

It would be highly desirable to provide a reliable mechanism which can anchor and stabilize the contact lens in a non-sliding alignment with the surgical area of the eye in a suture-free, non-invasive and trauma-free fashion, without the need for manual repositioning and centralization of the contact lens (and/or contact lens holder) during the operation.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a contact lens assembly for ophthalmic procedures which is capable of attaining a non-sliding non-sutured hand-free operation for the lens stabilization and centralization during a vitreoretinal surgery.

It is another object of the present invention to provide a contact lens assembly equipped with a reliable anchoring system capable of hands-free stabilization and centralization of the contact lens assembly at a desired site of procedure in a non-sutured trauma-free manner.

In one aspect, the present invention is directed to a contact lens assembly for ophthalmic procedures, which comprises an optical element (such as a contact lens), a contact lens holder, and an anchoring/stabilizing mechanism configured to anchor and stabilize the contact lens at the surgical site without the need for a surgeon to manually adjust the position of the contact lens during the procedure.

The anchoring mechanism is contemplated in various configuration, for example, realized as the magnetically actuated anchoring/stabilizing mechanism, or implemented with microstructures disposed at predetermined positions on the eye contact surface of the optical element (or the bottom surface of the contact lens holder) which creates an anchoring action for the optical element at a desired procedure site when the microstructures are brought in contact with tissues of the eye (such as the superficial layer of the eye cornea) during an ophthalmic procedure, or equipped with a mechanism for securing the contact lens (or the contact lens holder) to the eyelid speculum for stabilizing the contact lens in place during the procedure.

In one aspect, the present invention is directed to a contact lens assembly equipped with a reliable and simple in use anchoring/stabilizing mechanist for ophthalmic procedures, which comprises an optical element (such as a contact lens) and an anchoring mechanism which constitutes a magnetically actuated connection for quick attachment of the contact lens to the eyelid speculum used on the ophthalmic procedure.

The subject anchoring mechanism may be configured with a pair of magnetically cooperating anchoring members (units), with one anchoring member being secured to the contact lens holder, while another being secured to the eyelid speculum used in the operation for the eyelid's displacement and stabilization. For being magnetically cooperative, the first and second anchoring members are fabricated from magnetically attractable materials selected from a group consisting of a magnetic material, metal (or ferrous) material, and their combination, meaning that at least one of the anchoring members is made from a magnetic material, while another can be made from a magnetic material or a ferrous material. For example, when the anchoring member secured to the contact lens holder is fabricated from a magnetic alloy, the anchoring member secured to the eye speculum may be manufactured either as a magnet or as a ferrous plate. When the magnetically cooperating anchoring members are brought into contact, they become magnetically engaged one with another, and thus anchor the contact lens in a stabilized position at the surgical site of the ophthalmic procedure.

The subject contact lens assembly for ophthalmic procedures comprises a contact lens (for example, corneal lens or a gonioprism contact lens) adapted for contacting an eye of a patient, and a contact lens holder secured (releasably or permanently) to the contact lens.

The eye speculum, which contributes to the subject anchoring mechanism, is configured with pair of radially spreading speculum arm members, each ending in a wire loop member, which are applied to the eyelids of a patient during ophthalmic procedure to displace and stabilize the eyelids.

The subject magnetically actuated anchoring mechanism is configured for retaining the contact lens assembly at a selected procedure site during the ophthalmic procedure, and is operatively coupled between the eye speculum and the contact lens holder (or the contact lens).

The anchoring mechanism includes a first and a second magnetically cooperating anchoring members, wherein the first anchoring member is secured to at least one of the wire loop members of the eye speculum, wherein the second anchoring member is operatively coupled to the contact lens holder (or the contact lens), and wherein, during the ophthalmic procedure, the first and second anchoring member are disposed in a magnetic contact one with another, thus releasably anchoring and stabilizing the contact lens at a desired position relative to the eye of the patient.

The subject anchoring mechanism further includes a wire member which is secured, at one end thereof, to the contact lens holder (or directly to the contact lens). The second anchoring member is attached to the wire member in a displaceable relationship therewith along the wire member.

Preferably, a rotational mechanism is operatively coupled between the wire member and the contact lens holder to support rotational displacement of the contact lens holder relative the longitudinal axis of the wire member for adjustability of the contact lens orientation. In addition, to enhance the positional adjustability, the contact lens is co-axially displaceable about the longitudinal axis of the contact lens holder.

The contact lens holder may be formed of a substantially cylindrical tubing for receiving the contact lens. The contact lens holder may be fixedly secured (releasably or permanently) to the contact lens at a periphery of the contact lens, and may be adhered to the contact lens at at least a portion of the contact lens periphery.

When, during the ophthalmic procedure, the pair of loop members of the eyelid speculum are radially displaced each from the other for maintaining the patient's eyelid in a stable displaced position, the first anchoring member is stably positioned at a predetermined placement at the eyelids.

In another aspect, the present invention is directed to a method for performing an ophthalmic procedure using a non-sliding non-sutured, hands-free contact lens assembly held in place with a reliable magnetically actuated anchoring/stabilizing mechanism.

The subject method includes the steps of:

configuring a contact lens assembly with a contact lens adapted for contacting an eye of a patient, and a contact lens holder secured to the contact lens;

configuring an eye speculum with a pair of speculum arm members, each terminating in a wire loop member, and a first magnetically cooperative anchoring member affixed at a predetermined position on a respective wire loop member; and

configuring a magnetically actuated anchoring mechanism between the contact lens assembly and the respective wire loop member of the eye speculum, wherein the anchoring mechanism includes the first magnetically cooperative anchoring member (on the eye speculum) and a second magnetically cooperative anchoring member secured to the contact lens assembly.

During the ophthalmic procedure, the subject method is supported by the following step:

placing said contact lens assembly over a desired procedure site;

applying the eye speculum to the eyelids to displace and stabilize the eyelids, thus securing the first magnetically cooperative anchoring member at a predetermined position;

bringing the first and second magnetically cooperative anchoring members in contact one with another;

performing the ophthalmic procedure; and

upon completion of the ophthalmic procedure, disengaging the first and second magnetically cooperative anchoring members, thus de-actuating the anchoring mechanism;

removing the contact lens assembly from the operational side; and

removing the eye speculum from the patient's eye.

These and other objects of the present invention will become apparent after reading further description of the preferred embodiment(s) of the subject invention in conjunction with the accompanying Patent Drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-**1**B are schematic representations of the subject contact lens (FIG. **1**A) and contact lens holder/assembly (FIG. **1**B) attached to the cornea of the eye during the surgical procedure;

FIG. **2** is a schematic representation of the subject gonioprism contact lens assembly attached to the eye during the surgical procedure;

FIGS. **3**A and **4**A are representative of the subject macular contact lens, where FIG. **3**A is a view of the subject lens from the bottom, and FIG. **4**A is a side view of the subject contact lens, showing microstructures placed on the bottom of the contact lens;

FIGS. **3**B and **4**B show an exploded view of the subject contact lens and contact lens/holder assembly showing micro structures formed on the bottom of the lens holder, where FIG. **3**B is a bottom view of the lens holder assembly, and

FIG. **4**B is a side view of the subject lens/holder assembly;

FIG. **5**A shows a cross sectional view of the subject contact lens and contact lens/holder assembly showing microstructures threadingly engaged with the subject contact lens;

FIG. **5**B shows a cross sectional view of the subject contact lens and contact lens/holder assembly showing microstructures fixedly engaged with the subject contact lens with a glue;

FIGS. **6**A-**6**B show an exploded view of the gonioprism contact lens assembly, where FIG. **6**A is a side view and FIG. **6**B is a bottom view of the subject gonioprism contact lens assembly;

FIGS. **7**A-**7**B show a side view (FIG. **7**A) and a bottom view (FIG. **7**B) of the subject gonioprism lens holder in an alternative embodiment;

FIGS. **8**A-**8**B represent the steps of the subject surgical procedure using the subject contact lens assembly with the macular (corneal) contact lens (FIG. **8**A) and with the gonioprism contact lens assembly (FIG. **8**B).

FIG. **9** is a frontal elevation view of an eye speculum used in conjunction with the subject contact lens and contact lens holder;

FIG. **10** is frontal elevational view of a stabilization mechanism to be coupled to the eye speculum as seen in FIG. **9**;

FIG. **11** is a frontal elevational view of the speculum assembly showing the stabilization mechanism in assembly with the speculum;

FIG. **12** is a cross-sectional view partially cut-away showing the sleeve member appendage inserted within a plate member of the speculum;

FIG. **13** an exploded view of the subject gonioprism contact lens assembly in an alternative embodiment showing the contact lens holder based magnetically cooperating member of the subject anchoring mechanism;

FIG. **14** is a frontal elevation view of an eye speculum modified for usage as a part of the subject anchoring mechanism in conjunction with the subject contact lens assembly; and

FIGS. **15**A-**15**C illustrate schematically an ophthalmic procedure using the subject alternative embodiment of the gonioprism contact lens assembly with the magnetically actuated anchoring mechanism, where FIG. **15**A depicts the modified eye speculum applied to the eye of a patient during an ophthalmic procedure to displace and stabilize the eyelids, FIG. **15**B depicts schematically the anchoring/stabilization of the subject contact lens assembly at the operational site through the magnetic connection between the speculum based anchoring member and the lens holder based anchoring member, and FIG. **15**C is a schematic representation of the subject gonioprism contact lens assembly secured to the eye during a surgical procedure by the use of the subject magnetically actuated anchoring mechanism.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. **1**A and **1**B show schematically the anchoring of the subject suture-free, non-sliding corneal contact lens assembly on the eye during an ophthalmic procedure. As shown in FIG. **1**A, the subject cornea contact lens assembly **10** includes a contact lens **12** removeably attached to the eye **14** by means of anchoring system **16** (which will be detailed in further paragraphs). Alternatively, as shown in FIG. **1**B, the subject contact lens assembly **10** for ophthalmic procedures includes the contact lens **12** and the contact lens holder **18** which receives the lens **12** and holds the entire system **10** in place during the ophthalmic procedure through the action of the anchoring system **20** on the bottom of the contact lens holder **18**.

As shown in FIG. **1**A, the anchoring system **16** is formed on the bottom **22** of the contact lens **12** in the form of microstructures **24** which, when brought into contiguous contact with the eye **14**, secure the contact lens **12** in place for the duration of the ophthalmic procedure.

As shown in FIG. **1**B, the anchoring system **20** is configured on the bottom **26** of the contact lens holder **18**. The anchoring system **20** is formed with microstructures **28** which, when brought in contiguous contact with the tissues of the eye **14**, maintain the contact lens holder **18** in position during the ophthalmic procedure, and thus supports the contact lens **12** at the desired site of operation.

The system **10** is a novel non-sliding corneal contact lens assembly equipped with the suture-free stabilization/anchoring system for vitreoretinal surgery which utilizes the microstructures **24** on the bottom **22** of the lens **12** or the microstructures **28** on the bottom **26** of the ring holder **18**. Microstructure **24** may be in numerous shapes, including, for example, micro-pins **30**, micro-grips, micro-barbs, micro-needles, or other textured microstructures on the bottom surface of the contact lens **12** or the contact lens holder **18**.

For the sake of simplicity and clarity of description, the microstructures **24** and **28** are described, as an example, in reference to the micro-pins **30**, although other microstructures on the bottom **22** of the lens **12** or the bottom **26** of the holder **18** are contemplated in the scope of the present invention. After the contact lens **12** is placed on the cornea **32** of the eye **14** and centered, a surgeon applies downward pressure on the contact lens **12**, which secures the lens **12** to the cornea **32**. The micro-pins **30** extend through a tear film **34** on the surface of the cornea **32** and a viscous coupling agent (solution) used during the procedure when applied to the ocular surface of the eye.

The coupling fluids applied on the surface of the tear film **34** during the procedure may be selected from a group of coupling fluids such as 2% methocel, thiol-tears gel, 1.4% sodium hyaluronate, 0.9% simple saline, and other contact solutions applicable to the purposes of the ophthalmic care using contact lens.

The micro-pins **30** extend through the tear film **34** and the viscous solution film **36** on the surface of the cornea **32**, and gently indent into the superficial cornea **32** without injuring it. A friction force is created between the lens' bottom surface and the coupling agent layer **36**, as well as superficial corneal layer **32**, by the micro-pins **30** indentation into the superficial cornea **32**, so that the contact lens **12** or the contact lens holder **18** is temporarily anchored to the cornea **32** for the duration of the ophthalmic procedure. After the ophthalmic procedure has been completed, the contact lens **12** and/or the lens holder **18** is lifted from the eye **14**.

Referring to FIGS. **1**A and **2**, the subject system **10** is also applicable for surgical gonioprism assembly **38** for glaucoma surgery, where a gonioprism contact lens **40** is used to obtain adequate visualization of the critical angle of the peripheral cornea to perform the micro invasive glaucoma surgery (MIGS) which includes implanting the stent or cutting into the trabecular meshwork. Glaucoma surgeons are generally opposed to placing fixation sutures during the glaucoma procedure in order to avoid trauma to the cornea or sclera of the eye. For this reason, the suture free system **38** of the current invention using a gonioprism contact lens **40** is highly desirable for use in ophthalmic procedures involving glaucoma surgical procedures.

As shown in FIG. **2**, the gonioprism contact lens assembly **38** includes the gonioprism contact lens **40** and the lens holder **42**. The bottom **44** of the lens holder **42** is formed with microstructure anchoring system **46** which may be in the form of micro-pins, micro-grips, micro-barbs, micro-needles or other textured elements formed on or attached to the bottom surface **44** of the lens holder **42**. The details of the gonioprism assembly **38** will be presented in further paragraphs.

Referring to FIGS. **1**A-**1**B, **3**A-**3**B and **4**A-**4**B showing the subject macular contact lens assembly **10**, the contact lens **12** may be used by itself or in assembly with the lens holder **18**. As presented in FIGS. **1**A, **3**A, and **4**A, the contact lens **12** is used by itself. The contact lens **12** is equipped with the anchoring system **16** configured with microstructures **24** on the bottom **22**. The micro-pins (or other microstructures) **30** are strategically placed on the bottom **22** of the lens **12**.

As shown in FIGS. **3**A and **4**A, the lens' bottom **22** is an eye contacting surface which may be shaped as a circular arc or in another suitable curved configuration to conform with the curvature of the eye cornea **32**.

The lens **12** has the upper surface **48** spaced from the bottom surface **22** by circumferentially extending walls **50**. The walls **50** of the contact lens **12** may form a cylindrical surface, trapezoidal surface, or other contoured surface as needed for specific optical properties of the lens **12**. The upper surface **48** of the lens **12** may be smaller than, larger than, or of the same size with the surface of the bottom **22** of the lens **12** (as dictated by the needed optical properties of the lens **12**).

The contact lens **12** may be manufactured from acrylic, glass, or other bio-compatible and optically viable materials used for the contact lens.

A number of micro structured elements **24** are provided on the bottom **22** of the lens **12**. The function of the microstructures **24** is to provide friction between the bottom **22** of the lens **12** and the cornea **32** in order to prevent sliding of the lens **12** from the desired surgical site, as well as to anchor the lens in place when the microstructures **24** (for example micro-pins **30**) penetrate through the viscous solution film **36** and tear film **34** and anchored to the superficial surface of the cornea **32**.

A number of micro-pins **30** are shown on the bottom **22** of the lens **12** which constitutes an anchoring system **16**. Although the number of micro-pins **30** shown in FIG. **3**A on the bottom **22** of the lens **12** is four, any other number greater than two may be used and is contemplated within the scope of the subject invention.

The micro-pins **30** may be manufactured from surgical steel, bio-compatible plastics or polymers, for example, PEEK (polyether ether ketone), or other bio-compatible materials.

The micro-pins **30** may be manufactured integral with the bottom **22** of the contact lens **12** (for example, by 3-D printing), or may be attached to the bottom **22** of the lens **12** via numerous mechanisms, including, for example, but not limited to, drilling, pressing, threaded engagement, thermo-soldering, coupling with the help of bonding agents (glue, adhesive), various interlocking mechanisms, such as, for example, interlocking tab and groove locking mechanism, etc. The microstructures may also be formed by chemical etching, chemical vapor deposition, plasma machining, photolithography, and other applicable processes.

For example, as shown in FIG. **5**A, openings **52** with the threaded walls **54** are pre-machined at the bottom **22** of the lens **12** to threadingly receive the micro-pins **30**. Alternatively, as shown in FIG. **5**B, the micro-pins can be glued in the openings **56** with glue **58** which may be, for example, a UV activated epoxy, or any other bio-compatible adhesive material.

Also alternatively to the drilling or gluing the micro-pins **30** into the bottom **22** of the lens **12**, the lens with the micro-pins (or other microstructures contemplated in the present invention for the purposes of stabilization, centralization, and prevention of the slipping of the lens from the desired surgical site) may be formed by a 3-D printer from a bio-compatible plastic, or like composition, for example, PEEK material.

The preferred diameter of the micro-pins (in their cross-section) may be in the range of 0.0012 inch, and can protrude from the surface of the bottom **22** of the lens **12** approximately 0.0013 inch to extend through the tear film **34** and viscous solution film **36** into contact with the cornea **32**. The micro-pins length from the bottom **22** to the exposed ends **60** thereof generally should not exceed 1 mm in order to prevent deep penetration into the cornea further than the corneal superficial layer.

The cross section of the micro-pins can be tapered down at the exposed ends **60** of the micro-pins **30**, or squared off.

Although shown as the same shape and same length in FIGS. **3**A and **4**A, the microstructures **24** also can be made of different shape and different dimensions, for example, as shown in FIG. **3**B.

Referring to FIGS. **1**B, **3**B and **4**B, the ophthalmic contact lens assembly **10** of the present invention includes the lens **12** and the lens holder **18**. In this arrangement, the stabilization, as well as centralization, of the ophthalmic contact lens system **10** at the desired site on the eye is provided by the anchoring system **20** configured on the bottom **26** of the lens ring holder **18**. As shown, the annular bottom surface **26** of the lens holder **18** includes microstructures in the shapes of micro-pins **30**, micro-grips, micro-barbs, micro-needles, or other textured micro-elements **24** positioned at a number of locations on the bottom **26** of the lens holder **18** around the periphery of the lens holder **18**.

The annularly shaped contact lens holder **18** has an annularly shaped bottom **26** (with concentrically spaced apart inner and outer peripheral edges) and an annularly shaped upper surface **62** (with concentrically spaced apart inner and outer peripheral edges). The circumferential outside walls **64** extend between the outer peripheral edges of the bottom surface **26** and the outer peripheral edges of the upper surface **62**.

Internal walls **65** extend between inner peripheral edges of the annularly shaped bottom surface **26** and upper surface **62**, respectively, of the holder **18**, and define a circularly shaped opening **66** therebetween.

The macular contact lens **12** is equipped with a flange element **68** which is formed integrally therewith or attached to the outer surface **70** of the circumferentially extending walls **50** of the lens **12**. The flange element **68** has a flange **72** extending from the outer surface **70** of the circumferential extending walls **50** of the lens **12**.

The bottom surface **22** of the lens **12** and the circumferentially shaped holder opening **66** of the lens holder **18** are shaped and dimensioned to correspond each to the other to permit the bottom **22** of the lens **12** to pass through the circumferentially shaped holder opening **66**. The flange member **68** is positioned around the outer surface **70** of the circumferentially extending walls **50** of the lens **12** a distance from the bottom **22** of the lens **12** corresponding to the height of the walls **64** of the lens holder **18** between the bottom surface **26** and the upper surface **62** thereof. When the contact lens **12** is received in the holder opening **66** of the lens holder **18**, the flange **72** of the flange member **68** is supported by the annularly shaped upper surface **62** of the lens holder **18**, thus preventing the contact lens **12** from displacing its bottom surface **22** below the bottom surface **26** of the lens holder **18**.

During the procedure, the lens ring holder **18** is positioned over the cornea **32**, and the lens **12** is received in the holder opening **66** of the lens holder **18**. The surgeon gently pushes down the contact lens/holder assembly **10**, so that the microstructures **28** on the bottom surface **26** of the lens holder **18** penetrate through the tear film **34** and viscous solution film **36** (as shown in FIGS. **1**B and **2**) and into the contact with superficial layer of the cornea **32** to gently indent into the cornea **32** without traumatizing the eye tissues to provide stabilization and centralization of the contact lens/holder assembly **10** in place and to prevent the deviation of the assembly **10** from the desired position during the ophthalmic procedure.

The lens ring holder **18** may be formed from polyether ether ketone (PEEK) material, or any other compound which is bio-compatible and capable of holding the contact lens **12** in position.

The height of the walls **64** of the lens holder **18** may be in the range of 1-2 mm, with the holder opening diameter ranging from 9 to 15 mm, for example, 11.5 mm.

The microstructures **28**, for example, micro-pins **30**, are formed along the circumference of the annularly shaped bottom **26** of the lens holder **18** in any manner similar to that described in previous paragraphs for the anchoring system **16** on the bottom **22** of the contact lens **12**.

A number of the micro-pins **30** on the bottom **26** of the lens holder **18** may range from 2 to 25 depending on the friction needed between the lens holder **18** and the tissues of the eye.

It has been experimentally concluded that the microstructures **24**, **28** can extend from the bottom of the lens **12** or from the bottom of the lens holder **18** no more than 1 mm in order to prevent excessive penetration and possible trauma to the surface of the tissues of the eye under surgery.

Referring to FIGS. **6**A and **6**B, as well as FIGS. **7**A and **7**B, the gonioprism assembly **38** includes a gonioprism contact lens **40** having a bottom surface **80** which is a circularly shaped surface configured to comply with the curvature of the eyeball. The gonioprism contact lens **40** has an upper surface **82** which is oval shaped and tilted as inclined with respect to the longitudinal axis **84** of the gonioprism contact lens **40**. Walls **86** extend in cylindrical contoured configuration between the edges of the bottom surface **80** and upper surface **82** of the gonioprism contact lens **40**.

The lens holder ring **42** includes an upper annularly shaped surface **87** and a bottom surface **88** which extend each from the other by a predetermined distance **90** defined by circumferentially shaped outer walls **92** of the gonioprism lens holder ring **42**. The outer walls **92** extend between the outer peripheral edges of the annularly shaped upper and bottom surfaces **87**, **88**, respectively.

The lens holder ring **42** further has inner walls **93** which extend circumferentially between inner peripheral edges of the annularly shaped upper and bottom surfaces **87**, **88**, respectively.

The inner walls **93** are contoured with a cylindrically shaped surface and define a holder opening **94** therebetween. The holder opening **94** in the lens holder ring **42** is shaped and dimensioned to correspond to the bottom surface **80** of the gonioprism contact lens **40**.

The circumferentially shaped outer walls **92** and inner walls **93** may be configured with an incision access cut-out **96** which may be a partial cut-out with a connecting element **98** extending along the edge of the upper surface **86** of the lens holder ring **42**.

Alternatively, as shown in FIGS. **7**A and **7**B, the lens holder ring **42** for the gonioprism assembly **38** may be similar to the lens holder **18** shown in FIGS. **3**B and **4**B formed as an annularly shaped lens holder with an opening **94** shaped and dimensioned for passing the bottom **80** of the gonioprism contact lens **40**.

In the arrangement shown in FIGS. **6**A and **6**B, the partial cut-out **96** is formed for surgical access/entry and visualization of the corneal incision. This cut-out **96** is positioned in relation to the site of the surgery so that the cut-out **96** is stabilized over the corneal or cataract incision. The modification of the gonioprism contact lens assembly **38** shown in FIGS. **6**A and **6**B permits the surgeon to view the incision site and to guide the surgical instrument into the anterior chamber of the eye for the ophthalmic surgery such as glaucoma surgery.

In the gonioprism assembly **38**, shown in FIGS. **6**A-**6**B and **7**A-**7**B, the bottom surface **88** of the lens holder ring **42** is provided with microstructured anchoring system **46** which, similar to that provided at the bottom **22** of the contact lens **12** and the bottom **26** of the lens ring holder **18** shown in FIGS. **1**A-**1**B, **3**A-**3**B and **4**A-**4**B, is manufactured with microstructures **28**, described in previous paragraphs.

Referring to FIG. **8**A, representative of the ophthalmic procedure supported by the use of the subject non-sliding, non-sutured hands-free contact lens anchoring assembly, the method begins in Step **1**, wherein the subject corneal (macular) contact lens assembly is formed which includes either the contact lens or the contact lens and the lens ring holder, where either the bottom of the lens is configured with the microstructure anchoring system or the bottom of the ring holder is configured with the anchoring microsystem. When the subject contact lens assembly is formed in Step **1**, the method advances to Step **2** where either the subject contact lens with the anchoring system on the bottom thereof, or the lens ring holder with the microstructured anchoring system on the bottom thereof is positioned above the desired surgery site on the eye.

From Step **2**, the operation follows to Step **3**, where a surgeon gently presses down either the contact lens to provide that the exposed ends of the micro-pins penetrate through the tear film and the viscous solution film, and in contact with superficial layer of the cornea.

In the procedure which uses the assembly of the contact lens and the lens ring holder, the contact lens is lowered into the opening of the lens ring holder. In both situations, the bottom of the contact lens comes into contact with the viscous solution film (when the solution is used for the procedure) or with the tear film.

In the following Step **4**, the surgeon performs the ophthalmic procedure such as vitreoretinal surgery or macular surgery. During the procedure, the subject contact lens assembly allows the surgeon to visualize the macular and other structures of the eye in high magnification. The contact lens assembly remains stabilized and centered on the cornea of the eye and is prevented from slipping from the desired surgical site.

Upon completion of the surgery procedure in Step **4**, the surgeon lifts the contact lens assembly from the eye, thus disengaging the microstructures from the tissues of the eye. The tissues of the eye are not traumatized by the micro-pins engagement therewith.

Following Step **5**, the subject assembly may be discarded (optionally) or sent for disinfection for use in other procedures.

During the Step **4**, the surgery is performed in a hands-free manner, when the surgeon (or the surgeon's assistant) does not have to manually locate and relocate the contact lens assembly. Non-sutured stabilization and centralization of the subject contact lens assembly and prevention from sliding from the desired surgical site is provided in the present method by the subject anchoring system formed at the bottom of the lens or at the bottom of the lens ring holder.

Referring to FIG. **8**B, in Step **1**, the gonioprism assembly is formed which includes a gonioprism contact lens and the lens holder ring, where a microstructured anchoring system is formed on the bottom of the lens holder ring.

Following Step **1**, the surgeon places the lens holder ring of the gonioprism assembly on the site of the surgery, lowers the gonioprism contact lens into the holder opening of the lens holder ring, and in Step **3** gently presses the lens holder ring down into the eye so that the exposed ends of the micro-pins (or other microstructures contemplated in the scope of the present invention) penetrate through the tear film and the viscous solution film of the eye as shown in FIG. **2**, and are in contact with a superficial layer of the eye tissue.

In Step **2**, the cut-out is positioned over the site of the corneal or cataract incision.

In the following Step **4**, the surgery (such as, for example, micro-invasive glaucoma surgery) is performed. During the surgery, the surgeon uses the subject gonioprism assembly in a hands-free manner without the need of stabilization and centralization of the gonioprism assembly by sutures. The sliding of the gonioprism assembly from the site of the surgery is prevented by the friction force provided by the microstructure on the bottom of the lens holder ring.

Upon completion of the surgery in Step **4**, the surgeon lifts the lens holder ring form the eye, thus disengaging the exposed ends of the microstructures on the bottom surface of the lens holder ring from the eye's tissues.

In Step **6**, following the removal of the gonioprism assembly from the eye, the gonioprism assembly can be optionally discarded or sent for cleaning and treatment for possible use in other procedures.

During an opthalmic procedure, it is important that that the contact lens be maintained in a stable, non-moveable positional location as the surgeon is operationally proceeding. In some cases the patient may tilt his/her head with a responsive tilting of the contact lens holder and the contact lens. This tilting causes unwanted gravitational assist forces to be applied to the contact lens and the contact lens holder which may, in some cases permit a displacement of the contact lens from the intended site.

Referring now to FIGS. **9**-**12**, there is shown a speculum assembly **100** to add further stabilization and non-displaceabilty of the contact lens **128** and the contact lens holder **130** which is seen in the operational combination in FIG. **11**.

The contact lens assembly of **100** includes a speculum of **104** seen in FIGS. **9** and **11**. Contact lens assembly or speculum assembly **100** includes speculum **104** and stabilization mechanism **106** to be further described in following paragraphs. Speculum or eye speculum **104** may be a standard eyelid speculum used for ophthalmic procedures which is commercially available and commonly known in the art. Speculum **104** may be of the type of that is commonly known as a "Lieberman eyelid speculum", although other speculums may be used in conjunction with stabilization mechanism **106**. For purposes of clarity and ease of understanding the "Lieberman" speculum will be used in further description.

Speculum **104** includes threaded member **108** for threaded engagement with plate member **118** of speculum **104**. Operationally, threaded member **108** may be rotationally displaced to displace threaded member **108** in a linear direction coincident with axis line **110**. A lower section (as seen in FIG. **9**) of threaded member **108** is coupled to bracket **122** which is reversibly displaceable along axis line **110**. Bracket **122** is pivotally connected to intermediate arm members **124** positioned on opposing sides of bracket **122** as is seen in FIG. **9**.

Intermediate arms **124** are respectively pivotally connected at pivots **126** to speculum arm members **112**. Speculum arm members **112** are pivotally coupled to plate member **118** on opposing horizontally displaced ends to permit radial displacement of speculum arm members **112** responsive to the rotation of threaded member **108**.

In this manner, rotation of threaded member **108** which is in threaded engagement with plate member **118** causes a linear displacement in axis direction **112** of bracket member **122**. Displacement of bracket member **122** being pivoted to intermediate arm members **124** which are in themselves pivoted being radially displaceable.

Loop members **114** are fixedly connected to respective speculum arm members **112** as shown. Loop members **114** are operationally used for bearing against the patient's eyelids to maintain the patient's eyelids displaced each from the other during the ophthalmic procedure. As speculum arm members **112** are radially displaced away from each other there is a respective displacement of loop members **114** away from each other. As previously described loop members **114** are adapted to contact opposing eye lids of a patient during the medical procedure and maintain the patient's eyelids in a relatively stable and spaced position.

Loop members **114** are generally wire members composed of a biocompatible solid material which has some flexibility such as stainless steel or some like composition not important to the inventive concept as herein described with the exception that loop members **114** are capable of accepting the loads imposed thereon.

Contact lens assembly **100** includes contact lens **128** which may in some cases be in the form of a geoprism lens as shown in FIG. **10**. Contact lens holder **130** as seen in FIGS. **10** and **11** is secured to a contact lens **128** through adhesive bonding or some other like technique. Contact lens holder **130** is fixed to contact lens **128** at least partially along a periphery of contact lens **128**. In this manner contact lens holder **128** is fixedly attached to to contact lens **128**. The function of contact lens holder **130** is to provide support and stabilization of contact lens **128** when contact lens **128** is positioned over a medical procedure site of a patient's eye.

Contact lens **128** may be of the type previously described in FIG. **3A**-**4B**. Contact lens **128** may include the anchoring mechanisms previously described to retain contact lens **128** at the selected procedure site during the ophthalmic procedure. Such an anchoring mechanism as previously described may include a plurality of microstructures located on the bottom surface of wall contact lens **128**. These microstructures may be selected from the group of micro-pins, micro-grips, micro-barbs, micro-needles, textured micro-elements as well as combinations thereof.

As described, contact lens holder **130** is fixedly secured to contact lens **28** throughout or at least a portion of the periphery of contact lens **130** as is seen in FIG. **10**. Contact lens holder **130** may be formed of a polygonal or circular cross-sectional contour tubing for matingly interfacing with contact lens **128**. As shown in FIGS. **10** and **11** contact lens holder **130** is formed by a substantially cylindrical tubing which receives contact lens **128**. However, the particular contour of contact lens holder **130** is not important to the inventive concept as herein described with the exception that it is adhered to at least a portion of contact lens **128** in order to securely hold contact lens **128** within contact lens holder **130**. Contact lens holder **130** may be composed of a solid composition which is bio-compatible, such as stainless steel or some like composition which is substantially rigid.

As more clearly seen in FIG. **10**, stabilization mechanism **106** includes flexible stabilization wire **132** having a stabilizing wire first ends **134** secured to contact lens holder **130** on opposing sides of lens holder **130** as is shown in both FIGS. **10** and **11**. Stabilizing wire first ends **134** may be adhered to lens holder **130** by adhesion or some like technique with the important consideration being that lens holder **130** is secured to stabilizing wire **132** at stabilizing wire first ends **134**. When taken in combination, contact lens **128**, contact lens holder **130**, and flexible stabilizing wire **132** form a closed contour.

Stabilizing wire **132** passes through a pair of sleeve members **136** which are mounted to and on opposing sides of stabilizing wire **132** which is clearly seen in FIG. **10**. Each of sleeve members **136** is formed of either an elastic composition such as rubber or in fact may be a formed of a bio-compatible composition which may be rigid. For purposes of illustration, sleeve member **136** is shown as being a substantially tubular contour. Sleeve members **136** are fixedly attached to stabilizing wire **132** by adhesive attachment or some like mechanism not important to the inventive concept as herein described. Each sleeve member **136** includes a respective sleeve member appendage or lug **138** extending from end of each of sleeve members **136** in the axial direction **110**. Sleeve member appendages **138** are fixedly secured to sleeve members **136** by being formed in one-piece formation with the sleeve members **136** or otherwise fixedly attached to respective sleeve members **136**.

Each end of plate member **118** is formed with a recess **140** within which respective speculum arm members **112** are pivotally connected as previously described. Thus the ends of plate member **118** take the form of a C-shape which provides a space between the speculum arm members **112** and the body of plate member **118**.

Sleeve member appendages **138** extending from an end of each of sleeve members **136** are insertable within opening or recess **140** of plate member **118** as seen in FIG. **12**. Sleeve member appendages **138** are inserted within plate opening **140** and may be wedged within plate opening **140** or otherwise secured thereto. In one aspect of system **100**, appendages or lugs **138** are frictionally secured within recesses **140** to permit easy removal of stabilizing mechanism **106** from eye speculum **104** subsequent to the ophthalmic procedure. Stabilizing wire **132** includes stabilizing wire upper section **142** and is adapted to extent over an upper surface of plate member **118** in a direction perpendicular to axis direction **110**.

In this manner there is formed a continuous stabilizing wire **132** contour extending from stabilizing wire first ends **134** to provide a continuous stabilizing wire **132** between stabilizing wire first ends **134** as is seen in both FIGS. **10** and **11**.

Stabilizing wire **132** includes a lower stabilizing wire section which passes between loop members **114** having inner loop sections **116** as is seen in assembly in FIG. **11**.

Operationally, when threaded member **108** is rotated, respective intermediate arm members **124** radially displace speculum arm members **112**. Stabilizing wire **132** is mounted within speculum arm members **112**, as is seen in FIG. **11** in operational combination. Stabilizing wire **132** is thus secured to eye speculum **104** between the displacement distance of inner loop sections **116** and may be essentially independent of the displacement of speculum arm members **112**.

Stabilizing wire **132** is fabricated from a malleable material such as stainless steel, a plastic composition or some like material which can hold its shape in a stable mode, but can be bent or flexibly displaced.

In this manner during an ophthalmic procedure, contact lens holder **130** and captured contact lens **128** are lowered onto the predetermined location desired in cooperation with the eye speculum **104**. If adjustments are needed to the positioning of lens holder **130**, the surgeon can simply apply pressure to a mid-section of stabilizing wire **132** to effect displacement of lens holder **130** and associated contact lens **128**. The adjustment pressure on stabilizing wire can be accomplished by the surgeon applying displacement force to the stabilizing wire **132** through the use of forceps contacting and applying pressure to opposing sides of stabilizing wire **132**.

In this manner, when a patient during a medical procedure tilts his/her head, the contact lens holder **130** and responsively the contact lens **128** are maintained in a stabilized position which acts against any gravity assist forces which may be encountered during the ophthalmic procedure.

FIGS. **13**, **14** and **15**A-**15**C show schematically the subject alternative system **200** for anchoring the corneal contact lens assembly on the eye **204** during an ophthalmic procedure. The present inventive concept is applicable to a wide variety of ophthalmic contact lens. However, as an example only, without restriction of the subject invention scope, the following paragraphs focus on a gonioprism contact lens assembly **206** shown in FIGS. **13** and **15**B-**15**C.

The subject gonioprism contact lens assembly **206** includes a gonioprism contact lens **208** to be removably attached to the eye **204** during an ophthalmic procedure by means of the subject magnetically actuated anchoring system (also referred to herein as the anchoring mechanism or anchoring. stabilizing mechanism) **210**, which will be detailed in further paragraphs.

The subject contact gonioprism lens assembly **206** for ophthalmic procedures further includes the gonioprism lens holder **212** which receives the lens **208** and holds the entire gonioprism contact lens assembly **206** in place during the ophthalmic procedure through the action of the anchoring system **210** provided in cooperation with the contact lens holder **212**. The anchoring system **210** may be provided in a direct cooperation with the contact gonioprism lens **208** or, alternatively, in a direct coupling with the lens holder **212**. As an example only, and not to limit the subject design to such particular configuration, the subject system will be further described with the focus mainly on the embodiment in which the subject anchoring system **210** can be coupled directly to the contact lens holder **212**.

The anchoring system **210** is configured with a pair of magnetically cooperating anchoring members (also referred to herein as units) **214** and **216**, which may both be fabricated from a magnetic material, or alternatively, one of the anchoring units **214**, **216** may be fabricated from a magnetic alloy, while another anchoring unit may be manufactured from a metallic material capable of magnetic attraction to the cooperating anchoring unit.

The subject anchoring mechanism **210** further includes a wire member **218** which is attached at the end **220** thereof to the contact lens holder **212** through a rotational mechanism **222**. The rotational mechanism **222** permits a bi-directional rotation of the lens holder **212** about the longitudinal axis **224** of the wire member **218** (shown by arrows A in FIG. **13**).

Alternatively, the wire member **218** may be attached directly to the contact gonioprism lens **208**. However, as an example only, but not to restrict the scope of the subject invention to this particular design, further description will focus on the design assuming the attachment of the wire member **218** directly to the lens holder **212**.

When the wire member **218** is held by a surgeon with the finger tips **215**, for example, in proximity to the end **226** of the wire member **218** (as shown in FIG. **13**), during positioning of the contact lens assembly **206** at the operational site, the surgeon can rotate the lens holder **212** (as well as the lens **208** attached thereto) about the longitudinal axis **224** of the wire member **218** to adjust the lens positioning. In addition, the lens **208** can be rotated bi-directionally within the lens holder **212** co-axially with the axis **217** (of the lens and the lens holder) along the arrows B (shown in FIG. **13**). The rotational displacement of the lens holder **212** relative the wire member **218**, as well as rotational displacement of the lens **208** co-axially within the lens holder **212**, provides a sufficient number of degrees of freedom for the contact lens **208** orientation adjustment which is highly beneficial for the lens holder positioning relative to the operational site.

An additional degree of freedom for adjustment of the subject contact lens assembly **206** positioning is beneficially provided by a displacement feature of the lens holder based anchoring member **216** along the wire member **218**. The magnetically attractable lens holder based anchoring member **216**, as shown in FIG. **13**, can be displaced bi-directionally along the wire member **218** in the directions C, as shown in FIG. **13**, thereby further promoting the adjustability of the relative positioning of the anchoring members **214** and **216** for an increased preciseness of positional placement and anchoring of the contact lens assembly in place.

The mechanism ensuring the displacement of the anchoring unit (member) **216** along the wire member **218** may be configured either by machining of a through opening within the anchoring member **216** for the wire member **218** to pass through to permit the anchoring member **216** sliding along the wire member **218**, or by providing a some sort of a rail structure for the anchoring member **216** displacement along the wire member **218**, or, alternatively, by forming a threaded engagement between the anchoring member **216** and the wire member **218** which can be transformed into a linear displacement of the anchoring member **216** along the wire member **218**. These and any other configurations permitting displacement of the anchoring member **216** along the wire member **218** are contemplated in the the subject system.

As shown in FIGS. **13** and **15**B, the anchoring unit **216** is attached to the wire member **218** at a predetermined distance from the end **220** thereof, and may be positioned in proximity to, or at the opposite end **226** of wire member **218**. As was indicated supra, the anchoring unit **216** can be displaced along the wire member **218** between the ends **220** and **226** to adjust position of the contact lens at the operational site.

The subject gonioprism contact lens assembly **206** cooperates with a speculum **230** shown in FIGS. **14** and **15**A-**15**B for realization of the subject anchoring mechanism **210**. In order to serve as a contributing element of the subject anchoring system **210**, the eyelid speculum **100** shown in FIGS. **9**-**11** has been modified. The modified speculum **230**, as shown in FIGS. **14** and **15**A-**15**B, is equipped with the magnetically attractable anchoring member **214** which may be fabricated either from a magnetic alloy, or a metal material (provided that the anchoring unit **216** is fabricated from a magnetic alloy).

The subject speculum **230** may be fabricated based on any type of the eyelid speculum, for example, the type that is commonly known as a "Lieberman eyelid speculum", although other speculums may be used in conjunction with the subject anchoring mechanism **210** in the subject system **200**. For the purpose of clarity and ease of understanding, the "Lieberman" speculum will be used in further description as the basis for the subject speculum modification.

The speculum **230** includes threaded member **232** for threaded engagement with a plate member **234** of the speculum **230**. Operationally, the threaded member **232** may be rotationally displaced to displace the threaded member **232** in a linear direction coincident with the axis line **236**.

A lower section (as seen in FIG. **14**) of the threaded member **232** is coupled to a bracket **238** which is reversibly displaceable along the axis line **236**. The bracket **238** is pivotally connected to an intermediate arm members **240** positioned at the opposing sides of the bracket **238** as is seen in FIG. **14**.

The intermediate arms **240** are respectively pivotally connected at pivots **242** to the speculum arm members **244**. The speculum arm members **244** are pivotally coupled to the plate member **234** at the opposing horizontally displaced ends **246** to permit radial displacement of the speculum arm members **244** responsive to the rotation of the threaded member **232**.

In this manner, rotation of the threaded member **232** (which is in a threaded engagement with the plate member **234**) causes a linear displacement in the axis direction **236** of the bracket member **238**. Displacement of the bracket member **238**, being pivoted to the intermediate arm members **240**, results in a radial displacement of the arm members **240**.

Wire loop members **248** are fixedly connected to respective speculum arm members **244** as shown in FIG. **14**. The wire loop members **248** are operationally used for bearing against the patient's eyelids to maintain the patient's eyelids displaced each from the other and stabilized during the ophthalmic procedure, as presented in FIGS. **15**A-**15**B.

As the speculum arm members **244** are radially displaced away from each other, there is a respective displacement of the wire loop members **248** away from each other. The wire loop members **248** are adapted to contact opposing eye lids of a patient during the medical procedure and maintain the patient's eyelids in a relatively stable and spaced position, as shown in FIGS. **15**A-**15**B.

The wire loop members **248** are generally wire structures composed of a biocompatible solid material which has some flexibility such as stainless steel or some like composition not important to the inventive concept, as herein described, with the exception that the wire loop members **248** are capable of accepting the loads imposed thereon.

In the subject system **200**, the modified eye speculum **230** is equipped with the magnetically attractable anchoring member **214** (also referred to herein as the speculum-based anchoring unit) which is attached to one of the wire loop members **248**.

The subject contact lens assembly **206** is a novel non-sliding corneal contact lens assembly equipped with the suture-free stabilization/anchoring system **210** for vitreoretinal surgery which utilizes the magnetic attraction between the magnetically cooperating anchoring units (members) **214** and **216**, where the unit **216** is a lens holder-based anchoring unit attached at the wire member **218** which is rotationally secured to the lens holder **212** (or to the gonioprism lens **208** itself), and where the speculum-based anchoring member **214** is secured to the wire loop member **248** of the eye speculum **230**.

In operation, as shown in FIG. **15**A, the eyelid speculum **230** is used by a surgeon in the ophthalmic procedure to widen and stabilize the eyelids **260**. When the eyelid speculum **230** is applied to the eyelids **260**, the anchoring member **214** attached to the wire loop member **248** is placed and remains at the predetermined position on the eyelid **260** of the eye **10** (shown in FIG. **15**A).

Subsequently, as shown in FIG. **15**B, the surgeon positions the contact lens holder **212** (along with the contact lens **208**) on the eye **204**, adjusts the positioning of the contact lens on the eye, as well as the position of the anchoring member **216** along the wire member **218**, and brings the anchoring member **214** and **216** in contact one with another (after adjusting positional placement of the lens holder-based anchoring unit along the wire member **218**). The anchoring members **214** and **216** are magnetically attracted each to the other, and, thus, anchor and stabilize the contact gonioprism lens assembly **206** in a stable position at the operation site in connection with the anchoring member **214** on the eyelid speculum **230** secured to the eyelid **260**.

For being magnetically cooperative, the first and second anchoring members **214**, **216** are fabricated from magnetically attractable materials selected from a group consisting of a magnetic material/alloy, metal (or ferrous) material/alloy, and their combination, meaning that at least one of the anchoring members is made from a magnetic material, while another can be made from a magnetic material or a ferrous material. For example, when the anchoring member **216** secured to the contact lens holder **212** is fabricated from a magnetic alloy, the anchoring member **214** secured to the eye speculum **230** may be manufactured either as a magnet or as a ferrous plate.

During positioning of the contact lens assembly **206** on the eye **204**, the surgeon can beneficially adjust orientation and position of the contact lens holder **212** due to the rotational mechanism **222** formed between the wire member

218 and the contact lens holder 212. After the contact lens assembly 206 is placed on the cornea 262 of the eye 204 and centered, the surgeon, by bringing the anchoring units 214 and 216 in contact one with another, secures the contact lens 208 to the cornea 262, and can perform the ophthalmic procedure in a "hands-free" fashion, as shown in FIGS. 15B-15C.

A viscous coupling agent (solution) 264 is used during the procedure when applied to the ocular surface of the eye, so the bottom of the lens 208 and the lens holder 212 may be in a direct contact with the solution applied on the surface of the eye for reducing sensitivity of the eye surface to the contact with the contact lens at the contact lens holder.

The coupling fluids 264 applied on the surface of the tear film during the procedure may be selected from a group of coupling fluids such as 2% methocel, thiol-tears gel, 1.4% sodium hyaluronate, 0.9% simple saline, and other contact solutions applicable to the purposes of the ophthalmic care using contact lens.

Although applicable to any contact lens and numerous ophthalmic procedures, as an example, the subject system 200 is described in the application for the surgical contact gonioprism assembly 206 for glaucoma surgery, where the gonioprism contact lens 208 is used to obtain adequate visualization of the critical angle of the peripheral cornea to perform the micro invasive glaucoma surgery (MIGS) which includes implanting the stent or cutting into the trabecular meshwork. Glaucoma surgeons are generally opposed to placing fixation sutures during the glaucoma procedure in order to avoid trauma to the cornea or sclera of the eye. For this reason, the subject suture-free system 200 of the current invention using the gonioprism contact lens 208 is highly desirable for use in ophthalmic procedures involving glaucoma surgical procedures.

A bottom 280 of the contact lens 208 is an eye contacting surface which may be shaped as a circular arc or in another suitable curved configuration to conform with the curvature of the eye cornea 262.

The gonioprism lens 208 has the upper surface 282 spaced from the bottom surface 280 by circumferentially extending side walls 284. The walls 284 of the contact lens 208 may form a cylindrical surface, trapezoidal surface, or other contoured surface as needed for specific optical properties of the lens 208. The upper surface 282 of the lens 208 may be smaller than, larger than, or of the same size with the surface of the bottom 280 of the lens 208 (as dictated by the needed optical properties of the lens 208).

The contact lens 208 may be manufactured from acrylic, glass, or other bio-compatible and optically viable materials used for the contact lens.

Referring to FIGS. 13 and 15A-15C, the ophthalmic contact gonioprism lens assembly 206 is anchored and stabilized, as well as centralized, at the desired site on the eye by the anchoring system 210 configured with the anchoring member 216 on the wire member 218 attached to the side wall 286 of lens holder 212, or, alternatively, to the side wall 284 of the gonioprism lens 208.

Alternatively, the wire member 218 may be attached by the end 220 thereof at another surface of the contact lens holder 212 (or the contact lens 208), such as, for example, the top surface 288 of the lens holder 212 or the upper surface 282 of the contact gonioprism lens 208.

As shown in FIG. 13, the annularly shaped contact lens holder 212 has an annularly shaped bottom 290 (with concentrically spaced apart inner and outer peripheral edges) and an annularly shaped upper surface 288 (with concentrically spaced apart inner and outer peripheral edges). The circumferential outside walls 292 extend between the outer peripheral edges of the bottom surface 290 and the outer peripheral edges of the upper surface 288.

Internal walls 294 extend between the inner peripheral edges of the annularly shaped bottom surface 290 and the upper surface 288, respectively, of the contact lens holder 212, and define a circularly shaped holder opening 296 therebetween.

The bottom surface 280 of the contact lens 208 and the circumferentially shaped holder opening 296 of the contact lens holder 212 are shaped and dimensioned to correspond each to the other to permit the bottom 280 of the lens 208 to pass through the circumferentially shaped holder opening 296.

Prior to the procedure, the contact lens holder 212 is positioned over the cornea 262, and the contact lens 208 is received in the holder opening 296 of the contact lens holder 212. The surgeon lowers the contact lens assembly 206 into contact with the tear film and viscous solution film 264 and brings the anchoring units 214, 216 in contact one with another (as shown in FIGS. 15B-15C).

During positioning of the contact lens holder assembly 206 on the eye 204, the surgeon can rotate the lens holder 212 relative to the wire member 218, as well as rotate the lens 208 inside the holder opening 296 in the contact lens holder 212, to adjust the position of the lens/lens holder relative to the patient's eye. When the anchoring units 214 and 216 are magnetically engaged one with another, stabilization and centralization of the contact lens assembly 206 in place is attained, and any deviation of the assembly 206 from the desired position during the ophthalmic procedure is prevented.

The lens holder 212 may be formed from polyether ether ketone (PEEK) material, or any other compound which is bio-compatible and capable of holding the contact lens 208 in position.

The height of the walls 286 of the lens holder 212 may be, for example, in the range of 1-2 mm, with the lens holder opening diameter ranging from 9 to 15 mm, for example, 11.5 mm.

As shown in FIG. 13, a partial cut-out 300 is formed in the lens holder 212 for surgical access/entry and visualization of the corneal incision. This cut-out 300 is positioned in relation to the site of the surgery so that the cut-out 300 is stabilized over the corneal or cataract incision. The configuration of the gonioprism contact lens assembly 206 shown in FIG. 13 permits the surgeon to view the incision site and to guide the surgical instrument into the anterior chamber of the eye for the ophthalmic surgery such as glaucoma surgery.

The ophthalmic procedure supported by the use of the subject non-sliding, non-sutured hands-free contact lens anchoring assembly is performed in the following sequence of operational steps:

The method begins in Step 1, wherein, as shown in FIG. 13, the subject corneal (macular) contact lens assembly 206 is formed which includes either the contact lens 208, or the contact lens 208 and the lens holder 212, and where the wire member 218 with the anchoring unit 216 is rotationally attached either to the lens 206 or the lens holder 212.

In Step 2, the modified eye speculum 230, shown in FIG. 14, is fabricated by securing the anchoring unit 214 (magnetically compatible with the anchoring unit 216 attached to the lens holder 212 via the wire member 218) to the wire loop member 248.

Subsequently, as shown in FIG. 15A, the subject method advances to Step 3 where the modified eye speculum 230 equipped with the anchoring unit 214 engages with the patient eye **204** to displace (widen) and stabilize the eyelids **260** as required by the ophthalmic procedure.

For being magnetically cooperative, the anchoring members **214**, **216** are fabricated from magnetically attractable materials, such as magnetic materials/alloys, metal (or ferrous) materials/alloys, and their combination, meaning that at least one of the anchoring members (**214** or **216**) is made from a magnetic material, while another can be made from a magnetic material or a ferrous material to serve as a coupling member (plate). For example, when the anchoring member **216** secured to the contact lens holder **212** is fabricated from a magnetic alloy, the anchoring member **214** secured to the eye speculum **230** may be manufactured either as a magnet or as a ferrous coupling plate. Reciprocally, when the anchoring member **214** is formed from a magnetic alloy, the anchoring member **216** may be formed as a metallic (ferrous) coupling member.

In Step **4**, subsequent to Step **3**, the subject contact lens assembly **206** equipped with the subject anchoring system **210** is positioned in alignment the desired surgery site. During Step **4**, shown in FIG. **15**B, the surgeon may effectively adjust the lens holder orientation relative the wire member **218** by rotating the lens holder **212** relative to the wire member **218**, as well as by rotation of the contact lens **208** within the opening **296** of the lens holder **212** (as shown in FIG. **13** by the arrows A and B). Additionally, the surgeon can displace the anchoring member **216** along the wire member **218** (as shown by the arrows C in FIG. **13**), for the benefits of the preciseness and convenience of the lens/lens holder positioning at the desired location.

Once the desired position and orientation of the contact lens assembly **206** is found in Step **4**, as shown in FIG. **15**B-**15**C, the surgeon brings the anchoring members **214** and **216** in contact each with the other to magnetically connect one to another, thus anchoring and stabilizing the position/orientation of the contact lens assembly **206** on the eye **204**, so that the surgeon can perform the ophthalmic procedure, such as the vitreoretinal surgery or macular surgery. During the procedure, the subject contact lens assembly **206** allows the surgeon to visualize the macular and other structures of the eye in high magnification. The contact lens assembly remains stabilized and centered on the cornea of the eye and is prevented from slipping from the desired surgical site.

The surgery is performed in a hands-free manner, when the surgeon (or the surgeon's assistant) does not have to manually locate and relocate the subject contact lens assembly. Non-sutured stabilization and centralization of the subject contact lens assembly and prevention from sliding from the desired surgical site is provided by the subject anchoring system supported by magnetic attraction between the anchoring members **214** and **216** secured, respectively, to the lens holder **212** and the eye speculum **230**.

Upon completion of the surgery procedure, the surgeon disengages anchoring member **214** and **216**, and removes the contact lens assembly **206** from the eye **204**. The tissues of the eye are not traumatized in any way by the subject anchoring mechanism.

Subsequent to the surgery, the subject assembly **206** may be discarded (optionally) or sent for disinfection for use in other procedures.

The contact lens holder **212** may be secured to the contact lens **208** through an adhesive bonding or some other like technique. Contact lens holder **212** is fixed to the contact lens **208** at least partially along a periphery of the contact lens **208**. In this manner, the contact lens holder **212** is fixedly attached to the contact lens **208**. The function of the contact lens holder **212** is to provide support and stabilization of the contact lens **208** when the contact lens **208** is positioned over a medical procedure site of a patient's eye.

The contact lens holder **212** is fixedly secured to the contact lens **208** throughout or at least a portion of the periphery of the contact lens **208**. The contact lens holder **212** may be formed of a polygonal or circular cross-sectional contour tubing for matingly interfacing with the contact lens **208**. The contact lens holder **212** is formed by a substantially cylindrical tubing which receives the contact lens **208**. However, the particular contour of the contact lens holder **212** is not important to the inventive concept as herein described with the exception that it is adhered to at least a portion of the contact lens **208** in order to securely hold the contact lens **208** within the contact lens holder **212**. The contact lens holder **212** may be composed of a solid composition which is bio-compatible, such as stainless steel or some like composition which is substantially rigid.

Although this invention has been described in connection with specific forms and embodiments thereof, it will be appreciated that various modifications other than those discussed above may be resorted to without departing from the spirit or scope of the invention as defined in the appended claims. For example, functionally equivalent elements may be substituted for those specifically shown and described, certain features may be used independently of other features, and in certain cases, particular locations of the elements may be reversed or interposed, all without departing from the spirit or scope of the invention as defined in the appended claims.

What is claimed is:

1. A contact lens system for ophthalmic procedures, comprising:

a contact lens assembly having a contact lens adapted for contacting an eye of a patient, and a contact lens holder secured to said contact lens;

an eye speculum configured with a threaded member extending in axial direction for radially displacing a pair of speculum arm members, each speculum arm member being equipped with a wire loop member secured at a distal end thereof, said wire loop member being applied to the eyelids of a patient during an ophthalmic procedure to displace and stabilize the eyelids; and,

a magnetically actuated anchoring mechanism operatively coupled between said eye speculum and said contact lens assembly, said anchoring mechanism including first and second magnetically cooperating anchoring members and a wire member secured, at one end thereof, to said contact lens holder, said first anchoring member being secured to at least one of said wire loop members of said eye speculum at a predetermined position thereat, and said second anchoring member being operatively coupled to said contact lens assembly and attached to said wire member in a displaceable relationship therewith along said wire member, whereby, during the ophthalmic procedure, said first and second anchoring members are disposed in a magnetic engagement one with another, resulting in an anchoring and stabilizing of said contact lens assembly at a desired position relative to the eye of the patient.

2. The contact lens system as recited in claim **1**, where said anchoring mechanism is configured for retaining said contact lens at a selected procedure site during said ophthalmic procedure.

3. The contact lens system as recited in claim **1**, further including a rotational mechanism operatively coupled between said wire member and said contact lens assembly, wherein said wire member defines a longitudinal axis along a length thereof, and said rotational mechanism supports rotational displacement of said contact lens assembly relative to the longitudinal axis of said wire member.

4. The contact lens system as recited in claim **1**, wherein said contact lens is coupled to said contact lens holder in a co-axial rotationally displaceable relation therewith about the longitudinal axis of said contact lens holder.

5. The contact lens system as recited in claim **1**, where said contact lens holder is fixedly secured to said contact lens at a periphery of said contact lens.

6. The contact lens system as recited in claim **5**, where said contact lens holder is formed of a cylindrical tubing for receiving said contact lens.

7. The contact lens system as recited in claim **6**, where said contact lens holder is adhered to said contact lens at at least a portion of said contact lens periphery.

8. The contact lens system as recited in claim **1**, where said pair of wire loop members extending at said respective speculum arm members are displaced each from the other for maintaining said patient's eyelid in a stable displaced position, and wherein said first anchoring member is stably displaced at a predetermined position relative to said eyelid during the ophthalmic procedure.

9. The contact lens system as recited in claim **1**, wherein each of said first and second anchoring members are fabricated from magnetically attractable materials selected from a group consisting of a magnetic material, metal material, and a combination thereof.

10. The contact lens system as recited in claim **9**, wherein one of said first and second anchoring members is fabricated from a metal alloy, and wherein another of said first and second anchoring members is fabricated from a ferrous material.

11. The contact lens system as recited in claim **1**,

wherein said contact lens is configured with a bottom surface configured for contact with the eye, an upper surface, and side walls extending circumferentially between an edge of said bottom eye contact surface and an edge of said upper surface; and

wherein said contact lens holder is an annularly contoured contact lens holder configured with:

an annularly shaped bottom surface having inner and outer concentrically spaced apart edges;

an annularly shaped upper surface having inner and outer concentrically spaced apart edges,

outer walls extending circumferentially along and between said outer edges of said annularly shaped bottom and upper surfaces, respectively, of said annularly contoured contact lens holder, and

internal walls extending circumferentially along and between said inner edges of said annularly shaped bottom and upper surfaces, respectively, of said annularly contoured contact lens holder and defining a holder opening therebetween, said holder opening being shaped and dimensioned in correspondence to said bottom surface of said contact lens.

12. The contact lens system as recited in claim **11**, wherein said contact lens is received in said holder opening of said annularly contoured contact lens holder and maintained with said bottom surface in contact with the tissues of the eye at the desired procedure site by said annularly contoured contact lens holder anchored at said desired procedure site by said magnetically actuated anchoring mechanism.

13. The contact lens system as recited in claim **11**, wherein said outer walls of said annularly contoured contact lens holder are shaped with a cut-out portion extending a predetermined length along said outer walls for surgical tools access and visualization of said desired procedure site.

14. The contact lens system as recited in claim **11**, wherein said annularly contoured contact lens holder is fabricated from a material selected from the group of: surgical steel, bio-compatible plastic, polyether ether ketone (PEEK), polymer, and combination thereof.

15. The contact lens system as recited in claim **1**, wherein said contact lens is selected from the group of a corneal lens and a gonioprism contact lens.

16. A method of performing an ophthalmic procedure, comprising:

configuring a contact lens assembly comprising:

a contact lens adapted for contacting an eye of a patient, and a contact lens holder secured to said contact lens;

configuring an eye speculum with a threaded member extending in axial direction for radially displacing a pair of speculum arm members, each terminating in a wire loop member at a distal end thereof,

securing a first magnetically cooperative anchoring member at a predetermined position on at least one of said wire loop members;

configuring a magnetically actuated anchoring mechanism operatively coupling said contact lens assembly and said respective wire loop member of the eye speculum, said anchoring mechanism including said first magnetically cooperative anchoring member, a wire member secured, at one end thereof, to said contact lens holder, and a second magnetically cooperative anchoring member operatively coupled to said contact lens assembly and attached to said wire member in a displaceable relationship therewith along said wire member;

placing said contact lens assembly over a desired procedure site;

applying said eye speculum to the eyelids to displace and stabilize the eyelids, thus securing said first magnetically cooperative anchoring member at a predetermined position at the eyelid;

bringing said first and second magnetically cooperative anchoring members in contact one with another to thereby magnetically engage one with another and anchor said contact lens assembly at a desired position relative to the eye of the patient;

performing said ophthalmic procedure;

upon completion of said ophthalmic procedure, disengaging said first and second magnetically cooperative anchoring members, thus de-actuating said anchoring mechanism;

removing said contact lens assembly from the operational side; and

removing said eye speculum from the patient's eye.

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